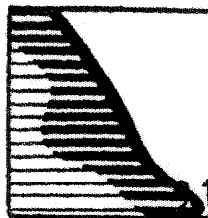


DIPLOMATE, AMERICAN BOARD  
OF PODIATRIC SURGERY



52 '01

FELLOW, AMERICAN COLLEGE  
OF FOOT & ANKLE SURGEONS

**DR. LESLIE S. AUFSEESER**

PODIATRIC PHYSICIAN AND SURGEON OF THE FOOT & ANKLE

October 26, 2001

Food & Drug Administration  
Dockets Management Branch  
Room 10-61  
5630 Fishers Lane  
Rockville, MD 20857

To whom it may concern;

On this 26th day, October 2001 Dr. Leslie S. Aufseeser submits this petition under the Department of Health, Education and Welfare, Food and Drug Administration (under 21CFR, Part 342) Docket number: 76N-0482 over the counter drugs, establishment of a monograph for over the counter topical antibiotic products.

To request the commission of food and drugs to amend a regulation order.

Action requested: Page 17651 under Skin Wound Protectants, third column under Category IA, Bacitracin (1). "Topical ointment dosage for both adults and children, should be not less than 500 units of Bacitracin per gram of finished ointment dosage form." I am requesting a change of this regulation to lower the amount of Bacitracin required to 44 units/gram.

Second Action requested: On the following page, under B, Polymyxin B sulfate. Under dosage, "Topical ointment dosage, for both adults and children, should be 4,000 to 5,000 units of Polymyxin B per gm. of finished ointment dosage form when used in combination." I am requesting that this be lowered to 892 units of Polymyxin B sulfate per gram of finished ointment.

B. Statement of grounds: I am a practicing podiatrist in the state of New Jersey. Beginning on or around January 1, 1990 I have been using a mixture of A & D ointment, Vitamin E oil and Polysporin Powder with the above mentioned amounts per gram of finished product to heal wounds of the lower extremity. This product has shown to heal approximately 90% of various types of wounds for which patients come to the office. Many of these patients are diabetic and many of these patients have poor circulation. A number of years back I petitioned the FDA to allow me to produce this product and sell it

**76N-0482**

**CP 7**

LAKEWOOD PLAZA • 1700 MADISON AVE. • LAKEWOOD, NJ 08701

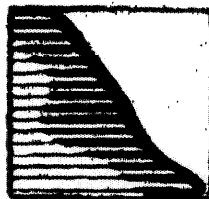
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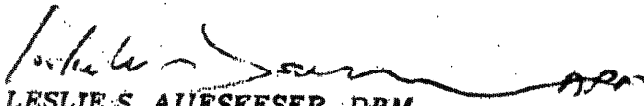
**DR. LESLIE S. AUFSEESER**  
PODIATRIC PHYSICIAN AND SURGEON OF THE FOOT & ANKLE

November 8, 2001

Food & Drug Administration  
Dockets Management Branch  
Room 10-61  
5630 Fishers Lane  
Rockville, MD 20857

To Whom It May Concern:

I certify there is no environmental impact on using Regenigel healing  
ointment.

  
LESLIE S. AUFSEESER, DPM

LSA/dd

to the public. I filled out a new drug application; I sent in numerous documentation to the FDA and I would like you to check this file and look at the information contained therein.

I have named the above mixture containing A&D Ointment, Vitamin E oil and Polysporin Powder ~~is~~ Regenigel Healing Ointment. Part of the information sent to the FDA contained a study of 67 patients approximately half were diabetic and approximately half had poor circulation. The ointment healed 92% of the wounds. There were virtually no side effects from using this ointment. One of the patients treated used the ointment for over one year until the ulcer on her heel healed. I did a second study from the years 2000 - 2001. In this study, 94 patients were reviewed with various types of ulcers. Enclosed is a brief summary of that study. The latter study had similar results. It healed 89% of the wounds. Some of the wounds that healed with this ointment according to our present knowledge, should not have healed. Some of these patients were diabetic with absent Doppler's to the digits that were ulcerated. According to the present knowledge, these would only heal with by-pass surgery.

I would like this ointment to be approved under the monograph for over the counter drugs. I would also accept it to be approved under a monograph for wound healing ointments. The present proposed rules require higher dosages of Bacitracin and Polymyxin B sulfate and therefore would require rejection under the topical antibiotic monograph. I, Dr. Leslie Steven Aufseeser certify that to the best of my knowledge and belief, this petition includes all information and views on which the petition relies and that it includes representative data and information known to myself, which are unfavorable to this petition.

  
SIGNED: \_\_\_\_\_

Dr. Leslie Steven Aufseeser  
1700 Madison Avenue  
Lakewood, NJ 08701  
732-367-5151

## REGENICEL HEALING OINTMENT

A & D Ointment:

Paraffin .5%  
Fragrance .125%  
Mineral Oil 2.4%  
Cod Liver Oil .937%  
Lanolin 15.5%  
Petrolatum 80.5%

Vitamin E:

141 I.U./gram of finished product

Polysporin Powder:

892 units polymyxin B-sulfate/gram of finished product  
44.05 units bacitracin zinc/gram of finished product



Regenicel Healing Ointment  
Second Clinical Study  
2000 - 2001

Leslie S. Aufseeser, D.P.M., F.A.C.F.A.S.  
1700 Madison Ave.  
Lakewood, N.J. 08701  
1-732-367-5151  
LSADPM@AOL.COM

Ninetyfour patients were treated using Regenicel Healing Ointment. This is a mixture of exact predetermined amounts of vitamin A@D ointment, vitamin E oil and Polysporin Powder. Any patient with a grade one to grade two wound regardless of vascular or medical status was accepted for treatment. Their diagnoses included diabetic ulcers, venous ulcers, traumatic wounds, delayed wound healing, wound dehiscence, abscess, thermal burn, vascular ulcers and decubitus ulcers. An eighty-nine percent success rate was obtained. Fortyfour of the ninetyfour patients or forty seven percent were diabetic. Sixty of the ninetyfour or sixtythree percent had absent palpable pulses. A number of patients had absent pulsatile flow when checked with dopler.

The average age was 74.06 years.

The average weeks till total healing was 8.15 weeks.

Thirtynine of the ninetyfour patients or 41% healed in one month or less.

The longest healing times were 65 weeks, 48 weeks, 30 weeks, 26 weeks and 22 weeks.

There were no adverse side effects from using Regenicel Healing Ointment.

Of the ten patients that did not heal patient #2 presented with chronic leg and ankle ulcers that were present for fifteen years. The ulcers improved during the four months of treatment, but patient withdrew from further treatment because the ointment was not covered by his insurance. Patient #17 presented with a necrotic diabetic right great toe ulcer associated with severe peripheral vascular disease. Regenicel maintained stability of the ulcer until she was seen by a vascular specialist. He prescribed saline wet to dry. The ulcer turned black. Patient underwent successful bypass surgery and amputation of the digit. Patient #18 was An 88 y/o diabetic with severe pvd. Patient was treated once with debridement and Regenicel. Patient decided to have bypass surgery which failed, was redone and patient died of heart failure. Patient #40 was a 77y/o with a left leg wound. Patient was allergic to sulfur. After two months patient was removed from this study. Patient #48 is a 78 y/o diabetic with absent pulses. She has a right midfoot dorsal ulcer 3cm. x 3cm.. Treatment began 3/6/2000. Patient did not heal but is stable and chooses to continue treatment. Patient #53 presented with a sub metatarsal I ulcer. Her M.D. stopped the Regenicel Ointment and prescribed bacitracin. When she then came back to me she had developed osteomyelitis of the first metatarsal. Patient #63 was an insulin dependant diabetic with a severely infected posterior leg ulcer. He required hospitalization and was healed with other methods. Patient #81 is a 77y/o with severe pvd and heart problems. Regenicel Ointment alternating with triple antibiotic ointment every 12 hours is keeping her stable. She is presently undergoing testing to see if she can be bypassed. Patient #86 is an 86y/o female with severe venous disease. Regenicel Ointment and unna boot treatment biweekly began 6/2000. This treatment is maintaining the health of these ulcers. Apligraf was tried twice as well. Patient #94 is a 37y/o female with vasculitis. Patient presented with a non-healing ulcer of her left leg secondary to a biopsy procedure. Regenicel is maintaining stability of this ulcer. Patient is set up for the application of apligraf, Novartis Pharmaceuticals Corp., East Hanover, N.J..

#### Treatment Protocol

All patients were evaluated and started on a program of good wound care. Necrotic tissue was debrided with a sterile #15 blade or small curette. Anesthetic block was administered as deemed necessary. Infections were treated with oral antibiotics. Most often used were levaquin 500mg daily, cephalexin 500mg t.i.d., clindamycin 300mg b.i.d., bactrim ds b.i.d. Diabetic and non diabetic ulcers were off loaded appropriately. Regenicel Ointment applied to an ulcer for three days without changing the dressing would soften necrotic tissue and allow easier debridement. Initially Regenicel would be applied daily with a sterile dressing. In wounds with little exudate the dressing would be left on for two days, sometimes three and then changed. A jar of ointment would be dispensed to the patient. The majority of patients would be seen weekly at my office for evaluation. Venous ulcers would require biweekly visits. 1% cortisone cream would be applied to the surrounding skin, Regenicel to the ulcer, sterile gauze and unna boot application. This treatment tried on a weekly basis did not work. A moist wound care environment should be maintained.

Regenigel Patient Study 2000-2001

#	AGE	Diabetic	PVD	WOUND TYPE	HEALED	Tx Failure
1	84		yes	ulcers left heel , leg 1.5 cms	22 weeks	
2	46			chronic ulcers of legs x 15 yrs		Pt. withdrew *
3	78		yes	ulcer under 1st met head L/F	13 weeks	
4	93			ulcer right leg 1-2 cms.	9 weeks	
5	85		yes	ulcer right foot 3-1.5 cms.	30 weeks	
6	85	yes	yes	ulcer right 3rd toe distal	2 weeks	
7	90	yes	yes	ulcer right bunion x 2mo.	6 weeks	
8	82			traumatic ulcer left leg	9 weeks	
9	79		yes	ulcer left leg	10 weeks	
10	53	yes		ulcer right midfoot- recurrent	different time periods	
11	84		yes	ulcer right hallux, heel, left ankle	26 weeks	
12	41			wound right ankle	1 week	
13	70	yes		non-healing incision right leg	5 weeks	
14	80	yes		traumatic ulcer right leg	5 weeks	
15	55	yes		non-healing incision with saline	2 weeks	
16	71	yes		full thickness skin loss left leg	12 weeks	
17	79	yes	yes	necrotic ulcer right hallux		yes
18	88	yes	yes	non-healing ulcer left heel		Pt. withdrew*
19	68	yes	yes	hallux ulcer	65 weeks	
20	82		yes	ulcer right foot-silvadene tx 6wks	9 weeks	
21	85		yes	ulcer left hallux	2 weeks	
22			yes	left heel ulcer whirlpool 3x/wkx6wk	11 weeks	
23	7			crushing wound R fifth toe	2 weeks	
24	81		yes	ulcer L bunion	3 weeks	
25	81			R ankle ulcer	1 week	
26	61	yes	yes	R hallux ulcer	3 weeks	
27	80	yes		L leg ulcer	6 weeks	
28	57			non-healing surgical wound L	2 weeks	
29	80	yes	yes	ulcer R hallux, fifth met	5 weeks	
30	71	yes	yes	ulcer R leg	2 weeks	
31	93			ulcers heels	2 weeks	
32	81		yes	L bunion ulcer	3 weeks	
33	86		yes	ulcer 4th toe left	3 weeks	
34	81	yes	yes	R 3rd toe ulcer	3 weeks	
35	81	yes	yes	abcess L hallux	48 weeks	
36	83		yes	ulcer left leg. on chemo	4 weeks	
37	83	yes	yes	heel ulcers	2 weeks	
38	69			ulcer L leg, allergy to sulfur	3 weeks	
39	83		yes	wound R leg	4 weeks	
40	77			ulcer L leg, allergy to sulfur		failed
41	81		yes	abscess R 4th toe	1 week	
42	84			ulcer L ankle	6 weeks	
43	69	yes	yes	ulcer R 2nd toe	9 weeks	
44	83		yes	L leg ulcer worse with neosporin	10 weeks	
45	82		yes	R bunion ulcer	3 weeks	
46	63	yes	yes	Ulcer L heel	10 weeks	
47	100	yes	yes	ulcers R ankle, L leg	7 weeks	
48	78	yes	yes	ulcer R midfoot		failed *
49	45	yes	yes	ulcer R hallux	19 weeks	
50	72	yes	yes	ulcer R hallux	11 weeks	
51	75	yes	yes	ulcer R foot	4 weeks	

52	63	yes	yes	ulcer L heel	12 weeks
53		yes	yes	ulcer sub met 1 L foot	failed *
54	37			ankle ulcers bilat	8 weeks
55	87		yes	ulcer L leg	10 weeks
56	85		yes	fissured heels	10 weeks
57	80			wound l leg	11 weeks
58	69	yes		R 2nd toe ulcer	9 weeks
59	75	yes		ulcer R foot	9 weeks
60	80	yes		ingrown R hallux nail, P@A	4 weeks
61	58	yes		ulcerated entire R leg	10 weeks
62	68	yes		ulcer R hallux	2 weeks
63		yes		ulcer L ankle	failed *
64	79	yes	yes	ulcer R ankle	26 weeks
65	64	yes		total nail excision	9 weeks
66	70	yes	yes	non-healing infected incisions R leg	6 weeks
67	50	yes		ulcer R 5th toe	4 weeks
68	91		yes	abscess l ankle, ulcer L hallux	5 weeks
69	45	yes		l leg wound	2 weeks
70	91		yes	ulcer r heel	3 weeks
71	79			avulsion R great toe nail	2 weeks
72	50	yes		ingrown toe nail p@a	4 weeks
73	78		yes	chronic leg ulcers	7 weeks
74	55	yes		post op wound r heel	8 weeks
75	73	yes		traumatic wounds legs, 6 wks neosp	4 weeks
76	89	yes	yes	abscess l bunion	5 weeks
77	83			l hallux ingrown toe nail	1 week
78	94		yes	abscess R 4th toe	3 weeks
79	91		yes	abscess R hallux	4 weeks
80	88	yes	yes	post-op wound R foot	8 weeks
81	73		yes	ulcer L leg	failed *
82	68			post-op incision abscess	2 weeks
83	81		yes	ulcer R leg	12 weeks
84	63	yes	yes	heel ulcers bilat	15 weeks
85	81	yes	yes	ulcer L hallux	48 weeks
86	86			ulcers L leg	failed *
87	81	yes	yes	ulcer R midfoot	19 weeks
88	83	yes	yes	ulcer L hallux	2 weeks
89	81	yes	yes	ulcer l foot sub met 5	7 weeks
90	73			abcess R 2nd toe	3 weeks
91	57	yes		ulcer R hallux	5 weeks
92	78	yes	yes	ulcer r 3rd toe 9 wks w neosporin	12 weeks
93	79		yes	ulcer L leg	11 weeks
94	73	yes		ulcers legs bactroban x 6wks	5 week-

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94	74y/o	46%D.M.	63%P.V.D.	8.15 wks
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**WOUND HEALING USING REGENICEL OINTMENT**  
**(A MIXTURE OF A&D OINTMENT, VITAMIN E, POLYSPORIN POWDER)**

**CLINICAL STUDY 1990 - 1997**

**LESLIE S. AUFSEESER, DPM, FACFAS**  
**1700 MADISON AVENUE**  
**LAKEWOOD, NJ 08701**

**732-367-5151**

From 1990 till March 1997 67 patients were treated using Regenicel Ointment. Their diagnoses included delayed wound healing, diabetic ulcerations, venous ulcerations, gouty ulcerations, trauma, wound dehiscence, abscess, thermal burn, vascular ulcers and decubitus ulcers. Regenicel Ointment is a combination of a broad spectrum antibiotic and nutritional supplements. A 92.5% success rate was obtained.

67 patients were treated at my office consisting of 161 treatment episodes. If a patient was healed and returned for a second problem, this was considered episode 2 etc.. 43% of the 67 patients were diabetic. 58% had absent palpable pulses. 48% of the 161 treatment episodes were diabetic patients. 63% of the 161 treatment episodes had absent pulses. Weeks till cure ranged from 1 to 111. The average week till cure was 8. If something healed in less than a week it was recorded as 1 week. There was no adverse reactions to the Regenicel Ointment. 40% or 27 of the 67 patients returned a second or more times for an additional problem. Treatment episodes ranged from 1 to 15 per patient. The average being 2.4 per patient. 21% of the treatment episodes healed in one week. Of 161 treatment episodes, a healed foot or leg was obtained 149 times, or 92.5%. Some of these patients had flat PPG waves to their digits and absent pulsatile doplers.

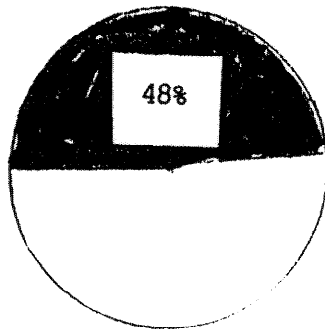
In the group that failed to heal Regenicel Ointment prevented the pathological area from worsening in most cases. Of the failures patient #4 died from complications of diabetes. Patient #7 had 2 treatment failure episodes. The first episode required 6 weeks of I.V. antibiotics to heal osteomyelitis of his third toe. The second treatment failure was related to cardiac end stage complications of diabetes. Patient #10 was slowly improving with Regenicel but grew impatient after three months of treatments. At this point in time she elected to have bypass surgery. Unfortunately she died from complications of the surgery. Patient #12 went for bypass after six months. Patient #17 is still being treated with Regenicel. She has gouty ulcers and severe peripheral vascular disease. The treatments are maintaining the health of the surrounding tissues and the ulcers are remaining small

and infection free. Patient #20 passed away before total healing could take place. Her photographs are included in this report. Patient #41 went for bypass surgery after left leg ulcer wouldn't heal. Three months later he developed gangrene on his right foot and refused surgical intervention. Patient #53 was saved with Regenicel treatments for many years. This 87 year old patient, having scleroderma and severe P.V.D. needed a left leg amputation. Patient #58 had nurses apply telfa over the Regenicel. This resulted in maceration of the tissues. After one week of this treatment I discontinued Regenicel and prescribed saline wet to dry. Patient #63 had gangrene of his heel, was a heavy smoker and had diabetes.

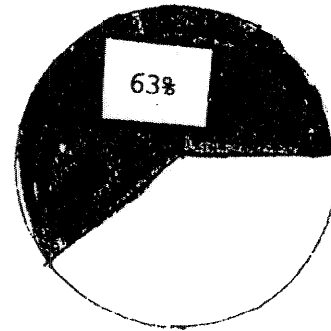
Regenicel Ointment was applied to the problematic area biweekly in most cases. If a patient could not return to my office biweekly the dressings would be changed after three to four days by the patient. Patient would then apply saline wet to dry dressings or antibiotic ointment and D.S.D. until the next visit. Presently patients are given Regenicel ointment to use at home.

If a wound was draining a lot, additional polysporin powder would be added to the ointment. Patients would be kept on antibiotics as needed. If an ulcer cultured methicillin resistant staph aureus, vancomycin powder would be sprinkled onto the ointment prior to its application. In recalcitrant cases vancomycin powder was added to the Regenicel Ointment. Very often these ulcers would then heal.

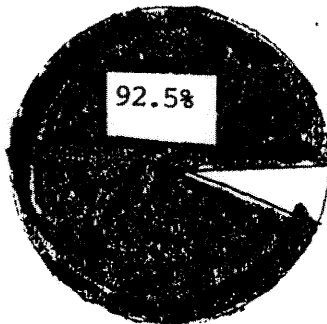
REGENICEL



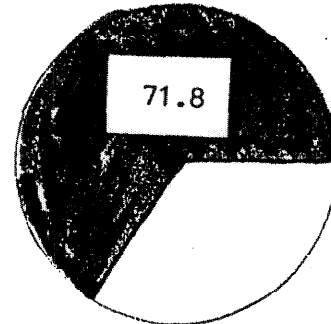
Diabetes



Absent  
Pulses



Wounds that  
Healed



Average age



## Patients

**PATIENT #1:** G.R. is patient number 1. Patient is a 58 year old diabetic, DP and PT pulses are absent, presented herself to my office January 11, 1994 with an ulceration on her right foot. Treatment consisted of debridement, application of Regenicel and patient placed on oral antibiotics. Treatment consisted of bi-weekly treatments of the application of Regenicel. Ulceration healed in 10 weeks.

**PATIENT #2:** G.G. is patient number 2. Patient is a 61 year old diabetic with absent pulses as well as experiencing rest pain. Patient came in March 15, 1990 with an infected small ulceration of the right heel. Regenicel was applied and patient was placed on Duricef. The ulceration healed in one week.

Same patient returned to my office 2 1/2 years later. Patient is now 63 years old with a chief complaint of having a large right heel ulceration. Regenicel treatment began October 19, 1992. This treatment consisted of bi-weekly treatments. This ulceration healed in 111 weeks.

**PATIENT #3:** W.J. is patient number 3. Patient is an 80 year old with absent pulses bilaterally. Patient first came to my office with ulcerations on both legs. Weekly treatments of Regenicel initially began November 1, 1990 and the first episode of healing occurred 13 weeks later.

Patient returned to my office February 28, 1991 with ulcerations on his left leg. Weekly treatments of Regenicel healed the ulcer in one week.

Patient then returned March 21, 1991 after sustaining trauma. There was an abscess on his left mid-foot. This was I & D'ed. Patient was placed on Cefin, Regenicel was applied. This healed in two weeks.

Patient had new ulcerations April 11, 1991. This healed in one week.

Patient had new ulcerations May 9, 1991. This healed in five weeks.

Patient had recurrent Cellulitis and ulcers June 27, 1991. This healed in three weeks.

Patient had abscesses on his leg August 1, 1991. These healed in 12 weeks.

Patient had Cellulitis in his leg January 30, 1992. Patient is now 81 years old. His legs healed in 3 weeks.

On March 5, 1992 patient had new ulcers on his legs. These healed in 13 weeks.

July 23, 1992, new ulcers on his left leg. These healed in three weeks.

September 3, 1992 new ulcer posterior left leg. This healed in six weeks.

November 12, 1992 new ulcers. This healed in 12 weeks.

February 11, 1993 patient sustained trauma to his legs. This healed in 9 weeks.

May 6, 1993 new ulcers on his left leg. These healed in 6 weeks.

July 1, 1993 new ulcers on his legs. These healed in 21 weeks.

**PATIENT #4:** J.B. is patient number 4. Patient first came to my office November 16, 1990 with a chief complaint of having cellulitis on her left 2nd toe. Patient is a diabetic. Weekly treatments of Regenicel healed the 2nd toe in two weeks.

Same patient returned September 3, 1991 with cellulitis in her right leg. Patient was placed on antibiotics. Patient healed in 2 weeks.

Same patient returned January 13, 1992. Patient is now 57 years old with an ulceration on the posterior aspect of her left leg which was present for approximately two weeks. Patient was placed on Clindamycin; the ulcer also was debrided, Regenicel was applied bi-weekly. Patient healed in 5 weeks.

Same patient returned May 28, 1993. She is now 58 years old. She has an infection on her right mid-foot. This was debrided, Regenicel was applied. Patient was placed on Clindamycin. This ulceration did not heal. Patient had to be admitted to Kimball Medical Center.

**PATIENT #5:** A.F. is patient number 5. This is an 83 year old patient with absent pulses and complaints of intermittent claudication. Patient first came to my office September 23, 1991 with an ingrown right hallux, fibula border. The abscess was incised and drained and patient was placed on Duricef. Regenicel was applied to the area. Healing occurred in one week.

Same patient returned January 3, 1994. Patient is now 86 years old. Chief complaint is an ulceration on the right 5th toe. Regenicel was started. Patient was placed on Cipro. Bi-weekly treatments healed the ulcer in 5 weeks.

Same patient returned May 10, 1994 with the same 5th toe ulcerated. Bi-weekly treatments of Regenicel healed the ulcer in 5 weeks.

**PATIENT # 6:** A.L. is patient number 6. This is a 63 year old, insulin dependent diabetic with absent pulses. Patient first came to my office April 9, 1992 with a fissured right heel and cellulitis. Patient was placed on Clindamycin, Regenicel was started bi-weekly and this healed in two weeks.

Same patient returned July 21, 1992 after sustaining trauma to his legs. Regenicel was begun bi-weekly. Patient was also placed on Clindamycin. This healed in two weeks.

Same patient came to my office August 21, 1992 after sustaining trauma to his left leg. Patient had a hematoma. This was incised and drained. Regenicel was applied. This healed in one week.

Same patient returned September 27, 1992 with an abscess of his left 3rd toe. The nail was excised. Regenicel was applied. Patient was placed on Cipro. Bi-weekly treatments healed this in 6 weeks.

Patient returned November 16, 1992 with new ulceration on his left leg. This healed in 5 weeks with Regenicel treatments.

Patient returned April 15, 1993 with an ulcer on his right foot. Bi-weekly treatment healed this in 5 weeks.

**PATIENT # 7:** M.R. is patient number 7. This is a 60 year old diabetic male with absent pulses. Patient first presented to my office April 17, 1992 with a distal right 3rd toe ulceration. Regenicel was applied. This healed in one week.

Same patient returned May 19, 1992 with an ulcer on the medial side of his left ankle. This was debrided, and Regenicel was applied. The ulcer healed in one week.

Patient returned April 20, 1993 one year later. Ulcer left leg. Regenicel was applied every three days. This healed in just over one week.

Same patient returned May 10, 1993. The right 4th toe was infected at this time. This was incised and drained. Patient was placed on Clindamycin, compresses, Bactroban. Patient returned three days later and then four days after that Regenicel bi-weekly treatments were begun. Ulcer failed to heal. Patient had to be admitted for intravenous antibiotics for six weeks to treat osteomyelitis of the distal phalanx. This toe was healed in three months.

Patient returned September 29, 1994 after sustaining trauma to the left hallux. Skin was degloved from the distal aspect of the toe. This was debrided. Regenicel was applied. Patient was instructed to treat the toe with saline wet to dry beginning the following day. After eight days the area was unimproved. At this time Regenicel treatments were begun. Patient was also placed on Cipro and Clindamycin. This eventually healed with the Regenicel treatments in one month.

Same patient returned February 7, 1995 with a fissure on his left hallux. This was debrided. Regenicel was applied. This healed in one week.

Same patient returned May 22, 1995 with an ulcer on the left ankle. Regenicel treatments were begun. This healed in two weeks.

Same patient returned July 24, 1995 with a right ankle ulceration. Regenicel was applied. Patient was placed on Clindamycin. This healed in one month.

Patient returned September 21, 1995 with a left ankle ulceration. Regenicel treatments were begun every three days. This healed in two weeks.

Patient returned October 13, 1995 with a new ulcer on the anterior aspect of his left leg. Regenicel treatments were begun. Because of patient's ill health, he was admitted to the hospital.

**PATIENT #8:** A.B. is patient number 8. Patient is a 73 year old diabetic with absent pulses. Doppler studies reveal a very faint posterior tibial pulse. PPG studies to the hallux reveal a flat wave. Patient first presented to the office on April 23, 1992 with an ulceration on the right hallux. This was present for approximately four months. Bi-weekly treatments of Regenicel were begun. This ulceration healed in 11 weeks. P.S. during treatment Porcine skin grafts with concomitant use of Regenicel were used in some of these treatment periods. Also Vancomycin powder was used during some of the visits with this patient.

Patient then returned April 23, 1993 with an ingrown tibial border, right hallux. The border was excised. Patient was placed on Cipro and Clindamycin. Regenicel treatments were begun. This healed in two weeks.

**PATIENT #9:** Z.P. is patient number 9, is an 82 year old female who came to my office August 21, 1992 with cellulitis on her right leg with small ulcerations. Patient was placed on Clindamycin. Regenicel was applied over the leg and ulcerations. An unna boot was applied over this. Patient was sent home and told to remove the unna boot in a few days and then to apply Mycolog b.i.d. Patient returned to the office September 8, 1992 and the leg was healed.

**PATIENT #10:** S.L. is patient number 10, is a 74 year old diabetic female with absent pulses bilaterally. Patient came to the office with an ulceration left first MP joint. Patient was placed on Regenicel treatments and antibiotics beginning October 2, 1992. This was healed one week later.

Same patient returned May 27, 1993 with an ulcer on her left forefoot, 2nd and 4th toes. Treatment began with saline wet to dry, Keflex and Mycolog. After one week this was switched to Regenicel treatments. Treatments continued for approximately three months. The hallux ulcer healed approximately six weeks after the treatment began. Patient developed paronychia on her left 2nd

toe which was incised and drained. Approximately 2 1/2 months after the initial treatment patient developed an ulcer over her bunion. Approximately 2 months, 3 weeks after the initial treatment began, patient developed a new ulcer on the dorsal aspect of her left hallux. The ulcers on her 2nd and 3rd toes and between the 3rd and 4th toes were very small at this point.

On September 2, 1993 patient went for by-pass surgery.

**PATIENT # 11:** J.G. is patient number 11. Patient is a 71 year old with absent palpable pulses. Patient presented himself to my office on December 11, 1992 with decubitus ulcer on his right heel. Patient was placed on Cephalexin which was eventually switched to Cipro and Regenicel treatments bi-weekly. The ulcer healed in three months.

**PATIENT # 12:** G.M. is patient number 12. She is a 67 year old diabetic with absent pulses. She presented herself to my office on January 15, 1993 with a left heel ulcer and a right hallux ulcer. Patient was placed on Bactrim DS and bi-weekly treatments of Regenicel. The left heel ulcer healed in one month. The right hallux ulcer failed to heal. On March 1, 1993 she developed an abscess on her right second toe. Treatments bi-weekly were given for six months and the ulcer on her right hallux did not heal. Patient went for by-pass surgery. The Regenicel treatments, even though they did not heal this ulcer, did stabilize the area and prevent it from getting worse during this six month period.

Same patient returned September 24, 1993 with the hallux re-ulcerated. Treatments at the office with Regenicel healed this ulcer in three months.

**PATIENT #13:** W.W. is patient number 13. This is a 64 year old male with severe peripheral vascular disease. On February 11, 1993 he had a diagnosis of gangrene of the right fifth toe, ulceration of the left heel and leg, a right hallux ulcer, a right ulcer below his knee area and a right fifth metatarsal ulcer. Regenicel treatments began on February 11, 1993 and continued bi-weekly. The ulcer below his right knee healed in two weeks; the fifth metatarsal ulcer healed in one month. At six weeks into therapy a partial ostectomy of the fifth toe was performed at my office. This ulcer healed at 10 weeks. All ulcers healed at four months.

On June 14, 1993 patient had a small left heel ulceration. This healed in one and one-half weeks.

On June 21, 1993 patient had a left leg ulceration. This healed in one week.

On July 2, 1993 patient had a right leg ulcer. This healed in two weeks.

**PATIENT # 14:** B.A. is patient number 14. She is a 92 year old diabetic with a diagnosis of gouty topos ulceration. On February 18, 1993 the ulcer was incised and drained. Regenicel treatments began bi-weekly. Patient's nurse's aide was given instructions on how to do the bi-weekly treatments and the ulcer healed.

Patient returned to my office December 23, 1993 with a gouty ulcer on her right third toe. This was also incised and drained. The area was injected with a cortisone preparation. Regenicel and a dry sterile dressing was applied and to be kept on for two days. Then the toe was treated with saline wet to dry and antibiotic ointment. The toe was healed one week later.

**PATIENT #15:** This is a male 75 year old insulin dependent diabetic. Presented himself to my office February 26, 1993 with delayed healing of right leg incisions. Regenicel was applied for four days, then saline wet to dry. The ulcerations were healed in one week.

**PATIENT #16:** G.F. is patient number 16. She is an 84 year old female with absent pulses. She presented herself to my office September 9, 1993 with paronychia of her left great toe. This was excised. Patient was placed on Cephalexin and Regenicel treatments bi-weekly. This area was healed in one month.

Patient then returned January 21, 1994 with an ulceration on her left fourth toe. Regenicel treatments were started and this was healed in one month.

Patient returned November 29, 1994 with an ulceration again on her left fourth toe. Treatments of Regenicel were started and the ulceration was healed in three weeks.

Patient returned March 23, 1995 with the same fourth toe ulceration. Regenicel treatments were started. This was to be continued by patient and the ulceration healed.

Patient returned February 3, 1996 with the same fourth toe ulceration. Regenicel treatments were initiated and continued by her visiting home nurse. The ulceration was healed in one week.

**PATIENT #17:** C.G. is patient number 17. She is an 88 year old female with severe peripheral vascular disease. She presented October 7, 1993 with ulcerations on her left hallux and 2nd, 3rd and 4th toes. The 4th toe had a gouty tophus. The right leg was amputated 2 1/2 years prior to this date. Patient was placed on Cipro and Regenicel treatments were started on this date and were continued bi-weekly. The 3rd toe was healed one month later. The 2nd and 4th toes were healed two months 1 week later, i.e. from the initial treatment of October 7, 1993.

On February 15, 1994 a diagnosis of interdigital tinea pedis was also added to her other diagnoses. Saline wet to dry, mystatin powder was prescribed.

On March 8, 1994 Regenicel was started again. At this point in time patient was being treated alternately with Regenicel and saline wet to dry for periods of time. Nine months from the original initial office visit all ulcerations were healed.

Patient then returned August 16, 1994, approximately six weeks later with new ulcerations on her left hallux, left 2nd and 3rd toes. Regenicel treatments were started bi-weekly and were continued at home by patient's health care provider. At eleven months after the above date, the ulcers were very small and stable.

**PATIENT #18:** M.P. is patient number 18. She is a 79 year old patient with a diagnosis of ulceration under her first metatarsal head, right foot. She has a palpable dorsalis pedis pulse. History also includes that of patient being in the hospital for one week approximately one month prior to coming to my office. The above ulceration was still draining. Treatment consisted of Clindamycin 300 mg. to be taken twice a day. The first treatment on November 4, 1993 consisted of debridement and application of Regenicel as well as a Dancer's pad to her insole. Patient was seen four days later and the ulcer was healed.

Patient returned February 5, 1994 with an ulceration again under her first metatarsal head, right foot. Regenicel treatments were started. This was left on for four days, and then patient was to apply saline and triple antibiotic ointment. The ulceration was healed at two weeks. On the visits where I saw patient, Regenicel was applied and left on for four days. Patient was then instructed to remove the dressings and did the saline and triple antibiotic ointment for three days until returning to my office.

**PATIENT #19:** J.K. is patient number 19. Patient is an 80 year old female with absent pulses. She presented herself to my office on March 1, 1994 with a non-healing ulcer on the dorsal aspect of her left foot. Ulceration was approximately 2 centimeters by 1 1/2 centimeters in size. Regenicel treatments began March 1, 1994 and continued bi-weekly. March 28, 1994 Regenicel was applied for three days, then patient was to apply betadine daily. May 9, 1994 the ulceration was just about totally healed. May 23, 1994 patient returned and the area was re-ulcerated. The treatments were started again. On July 26, 1994 five months from the first treatment at my office, the area was healed.

**PATIENT #20:** E.M. is patient number 20. She is a 78 year old female with absent pulses. She presented herself to my office on March 8, 1994 with an infected left hallux since December 1993. Her right leg was amputated for a diagnosis of uncontrolled infection, osteomyelitis. The left hallux had osteomyelitis and patient also had a third toe ulceration. On March 8, 1994 I excised patient's nail on the left hallux as well as all devitalized bone. Patient was placed on Clindamycin and Regenicel treatments were started. Patient was seen that same day at 6 p.m. The packing was removed and replaced, and Regenicel ointment re-applied. Patient was seen the following day, March 9, 1994, and then again March 11, 1994, and then three days after that which was March 14, 1994, then bi-weekly. Approximately one month after the initial treatment date the third toe was healed and the hallux was almost healed. Treatments continued bi-weekly and I treated patient approximately five months from the initial office visit. The toe never totally healed. Patient passed away.

**PATIENT #21:** D.R. is patient number 21. She is a 75 year old insulin dependent diabetic. She presented herself to my office on June 7, 1994 with a diabetic ulcer on her left mid-foot area. Patient was placed on Clindamycin and Regenicel treatments were started bi-weekly. Three months, one week into the treatment period, a partial osteotomy was performed on this area. At three months, three weeks, from initial treatment date, the ulcer was healed.

**PATIENT #22:** S.B. is patient number 22. He is a 55 year old diabetic male who presented himself to my office on June 28, 1994. He had been seeing a vascular doctor for treatment of an ulceration

on his right foot since March without resolution or healing of the ulceration. Regenicel treatments began June 28, 1994. The ulceration was well healed after one month.

**PATIENT #23:** F.E. is patient number 23. She is a 96 year old female with an ulceration on her right ankle. Regenicel treatments began February 3, 1995. The Regenicel was dispensed to the patient for bi-weekly treatments. The ulceration was just about totally healed after two weeks.

This same patient returned July 27, 1995 with a diagnosis of decubitus ulcers, bilaterally. Patient was a resident at the Bey Lea Nursing Home. Regenicel treatments were started. After six weeks of treatment, the right ulcer was almost totally healed and the left ulceration had a clean base. At this point, patient passed away.

**PATIENT #24:** D.D. is patient number 24. She is a 74 year old female with absent pulses. Also noted is that her toes are blue in color. She presented herself to my office on March 28, 1995 with an ulceration on her left fourth toe. Patient was placed on Cephalexin and Regenicel treatments bi-weekly. Approximately one week later patient was hospitalized for a medical problem. Patient returned on June 2, 1995 for treatment of a chronic fourth toe ulceration, left foot, as well as an ulceration on the plantar aspect of her right foot under the fifth metatarsal head. Again, patient was placed on Cephalexin and the Regenicel treatments bi-weekly. Approximately one month later, the ulcerations were almost totally healed.

**PATIENT #25:** K.I. is patient number 25. He is a 74 year old diabetic. He presented himself to my office on October 5, 1995 after sustaining trauma to his left leg. He had an infected ulceration on the left leg. Patient was started on Regenicel ointment to be left on for three days, then patient was to apply antibiotic ointment daily, and to return to the office one week later. After one week of treatment, I debrided the ulcer and again the above treatment regimen was repeated, i.e. Regenicel for 4 days, then antibiotic ointment daily by the patient. I saw patient back October 19, 1995, two weeks after the original treatment date and the ulceration was just about healed. The treatment was again performed on this date, and the ulcer went on to heal.

**PATIENT #26:** A.M. is patient number 26. He is a 59 year old insulin dependent brittle diabetic. Patient had blood sugars ranging from 600 mg. to at one point 1200 mg. Patient is also bed-ridden. I saw patient first on December 3, 1995 with severe decubitus ulcerations on both heels as well as multiple ulcerations on both legs. The left heel had possible osteomyelitis. Regenicel treatments were started on December 3, 1995. Approximately one month later, all ulcers were smaller and cleaner. Bi-weekly treatments of Regenicel were continued. January 18, 1996 patient was ill and was sent to the hospital.

**PATIENT #27:** W.F. is patient number 27. Patient is a 61 year old male who had osteomyelitis of his 5th metatarsal head, right foot. Patient had the 5th metatarsal head excised at Kimball Medical Center August 2, 1996. The wound was packed open. One week post-op, the wound was healing well and was seen by another podiatrist who told patient to return in one week to evaluate for delayed primary closure vs. secondary intention healing. I saw patient August 16, 1996. Regenicel was started at this time. The patient was seen three days later. The wound was almost totally



healed. Regenicel was re-applied times 3 days, then patient was to apply Silvadene daily. I saw patient one week later. The wound was totally healed.

**PATIENT #28:** N.M. is patient number 28. Patient is a 75 year old male with severe peripheral vascular disease. Patient presented himself to my office with an ulceration on his left fourth toe, left second toe, and right second toe. Regenicel treatment began on March 15, 1996. After one week, the second toe ulcer on the left foot healed. After three weeks, the right second toe ulcer healed. Four and one-half months the fourth toe ulceration on the left healed. Vancomycin powder was added to the Regenicel because of a Methicillin resistant Staph aureus positive culture taken at the office.

**PATIENT #29:** T.M. is patient number 29. This is a 31 year old black male with a diagnosis of venous ulcer on his right ankle. Ulcer began approximately February 2, 1992. Patient was being treated at the Mercer Wound Care Center from February 4, 1994 until September 1, 1995 with Procurin therapy. I first treated patient on September 1, 1995 with Regenicel and unna boots. The ulcer healed in three weeks.

I saw patient again on December 5, 1995 for the same re-ulcerated venous ulcer. I applied Regenicel and an unna boot. This was applied bi-weekly; subsequently weekly. The ulcer healed in three and one-half weeks.

May 20, 1996 a small ulcer on the right ankle developed. Regenicel was applied bi-weekly. The ulcer healed in two and one-half weeks.

August 15, 1996 the area began to re-ulcerate. Treatment of Regenicel healed the area.

**PATIENT #30:** R.H. is patient number 30. Patient is a 65 year old diabetic male with absent pulses. Doppler studies confirm absent DP and PT pulses bilaterally. Patient is also on chemotherapy. Patient first came to my office May 21, 1991 with an infected left hallux. I treated him with penicillin, pedi-boro soaks. After one week, Regenicel was applied and the toe healed soon after.

Patient returned to my office January 31, 1992 with a small right hallux ulcer. Regenicel was applied and patient was placed on Clindamycin. The ulceration healed with one treatment.

Patient returned February 7, 1992 with a right third toe infection. Regenicel was applied. Patient was placed on Cipro. The ulceration healed in one and one-half weeks.

Patient returned February 20, 1992 with a fissure on his right forefoot. Patient was placed on Keflex. Regenicel treatments were started bi-weekly. The fissure healed in about three weeks.

Patient returned March 18, 1992 with a re-ulcerated left hallux secondary to playing golf. Patient was started on bi-weekly Regenicel treatments. On March 27, 1992 Vancomycin powder was added to the Regenicel. The ulcer healed in two and one-half weeks.

Patient returned April 13, 1992 with an abscess on his right third toe. Regenicel treatments were started. The third toe infection was healed in three weeks.

Patient returned March 1, 1993 after sustaining trauma to his left hallux. On March 1, 1993 I did an incision and drainage. Patient was placed on Clindamycin and saline compresses. On March 5, 1993 Regenicel was started. One week later the left hallux was healed.

Patient returned May 11, 1993 after scraping the plantar aspect of his right foot. Regenicel was immediately applied to the scrape and it healed with one treatment.

Patient returned May 2, 1994 after sustaining trauma to his left hallux. The nail plate was excised. Regenicel was applied. Patient was placed on Cephalexin. After two weeks, the left hallux was healed. P.S. Cipro was added to the above treatment after one week on Cephalexin. Vinegar wet to dry compresses were used in the latter half of the above treatment period.

Patient returned January 13, 1995 after sustaining trauma to his right third toe. On January 13, 1995 I did an incision and drainage. Patient was placed on Cephalexin and Regenicel treatments. Regenicel was applied for two days, patient did saline compresses for two days, etc. On January 20, 1995 patient had to be admitted to the hospital for medical treatment, but the toe was almost totally healed.

June 9, 1995 patient returned after sustaining trauma to his left hallux. One treatment of Regenicel healed the above.

Patient returned to my office on November 28, 1995 after sustaining trauma to his right second toe. This was a golf related injury. I did an incision and drainage. Patient was placed on Clindamycin and Regenicel treatments. December 4, 1995 patient re-injured the area playing golf. Regenicel was continued. Patient was now on Ciprofloxacin. December 12, 1995 patient was placed on Clindamycin. December 22, 1995 patient sustained trauma to his left hallux. Regenicel treatments continued. January 9, 1996 patient was placed on Trental. January 12, 1996 patient was placed on Cipro. Vancomycin powder was added to the Regenicel. On January 16, 1996 the left hallux was healed. The hallux healed in three weeks. Weekly Regenicel treatments were continued for the right second toe. February 2, 1996 p.o. vitamins were added to the therapy as well as muscle stimulation. Ultrasound was administered to his legs as well as applying vitamin oils.

February 23, 1996 patient had an ingrown infected left hallux tibial border. Regenicel treatments continued.

On March 11, 1996 patient was admitted to the hospital for insulin therapy.

On March 18, 1996 patient had a left third toenail abscess. This was incised and drained.

On March 2, 1996 a Dr. Chew, who is a vascular specialist, recommended by-pass surgery and possible amputation of the right second toe. I did a nerve block on the left side. On March 25, 1996

the right second toe was just about totally healed, the left fourth toe was healed, the left hallux was un-improved at this point.

On March 29, 1996 a PPG study showed a faint flow to the left hallux.

April 4, 1996 the right second toe was totally healed. This took four months and one week of bi-weekly Regenicel treatments.

April 12, 1996 the right second toe was slightly re-ulcerated. Bi-weekly Regenicel treatment healed this in three weeks.

April 22, 1996 patient had a second opinion from another vascular doctor and he was told he could not have by-pass surgery.

May 6, 1996 the patient had distal gangrene of his left hallux which was well circumscribed. Weekly Regenicel treatments continued.

May 31, 1996 a Dr. Samson, who is another vascular doctor recommended debridement of the left hallux. He told patient the bone was infected and told patient to have a bone scan. Patient did have a Technetium Bone Scan and the scan was negative.

June 10, 1996 Doppler's and PPG studies were re-done on the left foot. There was no pulsatile flow with the Doppler's, and the PPG showed a flat wave to the hallux.

August 13, 1996 patient went for an arteriogram. Dr. Samson, a vascular specialist wanted to do by-pass and gave patient a 50-50 chance for success.

September 14, 1996 I did a partial ostectomy of the distal phalanx. This was packed with sterile packing. I saw patient later in the day. The packing was removed and the wound was partially closed with steri-strips, Regenicel ointment was applied over the steri-strips. This treatment continued

December 27, 1996 the hallux was almost totally healed. As of March 28, 1997 there was approximately 5 millimeter opening on the distal aspect of the left hallux. Regenicel treatments have maintained the health of this area. On April 5, 1997 the hallux was totally healed.

**PATIENT #31:** J.M. is patient number 31. Patient is a 62 year old diabetic with palpable pulses. Patient presented herself to my office on July 12, 1996 with an ulceration on her hallux. I started patient on Clindamycin and Regenicel treatments. Two months later the ulceration appeared to be totally healed.

August 16, 1996 hyperkeratosis over this same site was debrided by myself. I examined the area under loop magnification and saw a very tiny ulcer present. Regenicel was again started. On September 3, 1996 it was totally healed.

**PATIENT #32:** A.G. is patient number 32. A 78 year old diabetic male with severe peripheral vascular disease. Patient presented himself to my office June 1, 1995 with an infected right great toenail. The nail was removed. I performed an incision and drainage of an abscess. Regenicel was started. A stat blood sugar revealed patient to have a blood sugar of 451 mg. Patient was referred to his medical doctor for diabetic control. The following day patient was to begin Pedi-boro compresses and Triple Antibiotic ointment. He went on to heal and was totally healed two weeks later.

Patient returned August 12, 1996 with an abscess on his right great toe. I performed an incision and drainage. Patient was placed on Cephalexin and Pedi-boro soaks. One week later a second incision and drainage was performed. Regenicel treatments were started. A week later the toe was healed.

**PATIENT #33:** A.M. is patient number 33. She is a 75 year old female with a chronic venous ulcer and cellulitis. She has been treated by the New Brunswick Wound Care Center for the past two months with unna boots and medication. May 9, 1995 Regenicel and unna boot therapy began as well as patient being placed on Clindamycin. These treatments were initially performed bi-weekly until patient improved, then treatments were performed on a weekly basis. Patient healed after four and one-half months of therapy.

**PATIENT #34:** G.K. is patient number 34. Patient is an 85 year old male with absent pulses. Patient presented himself to my office on August 13, 1996 with a staph infection on his left leg as well as a superficial ulceration. Regenicel treatments were started. Patient was placed on Cephalexin. Patient healed in one month.

**PATIENT #35:** Patient is a 61 year old female that has liver cirrhosis. She presented herself to my office on October 6, 1995 with bilateral leg ulcerations. Ulcer on her left leg was approximately 5 cm. x 3 cm. in size. This was over the anterior tibial area. Regenicel treatments began on this date. All ulcerations were healed after eleven months.

**PATIENT #36:** W.S. is patient number 36. This is a 60 year old diabetic who is post-op fifth toe amputation. He presented himself to my office August 23, 1996 six weeks after having his fifth toe amputated. He had been treated by a wound care center. The ulcerations remained. Regenicel treatments were started. Patient was placed on Ciprofloxacin, and also was receiving IV Vancomycin for two more weeks. Treatments of Regenicel healed the above ulcerations in one month. One week prior to total healing of the above ulcerations, the wound care center was still recommending Procurin therapy.

The above patient returned to my office on October 24, 1996 after placing his right foot in scalding hot water. He sustained first and second degree burns to his entire right foot area up to the ankle region. He was placed on p.o. antibiotics and Regenicel ointment was applied to the entire burned foot. He was seen daily at my office. Blisters were incised and drained and devitalized tissue was debrided as needed. In three and one-half months, patient was totally healed.

**PATIENT #37:** J. P. is patient number 37. She is a 55 year old diet controlled diabetic who had undergone surgery on her right hallux and her right second and third toes. Mild wound dehiscence occurred on post-op day two, Regenigel ointment was applied. Approximately one week later, the skin reverted back to normal.

**PATIENT #38:** C.A. is patient number 38. This is a 72 year old female with a chronic ulcer on her right ankle that other doctors could not heal. On April 7, 1994 bi-weekly Regenigel treatments were started. Patient was also placed on one week of Ciprofloxacin. The ulcer healed after five weeks.

The same patient returned August 12, 1996 after sustaining trauma to her right ankle. The above ulcer re-ulcerated. Regenigel treatments were started. The ulcer healed in two weeks.

**PATIENT #39:** L.P. is patient number 39. This is a 72 year old male with a venous ulcer that has been present for the past five years. Patient has absent pulses. On July 22, 1996 Regenigel treatments were started. The ulcer healed in six weeks.

**PATIENT #40:** F.M. is patient number 40. This is a 75 year old female with absent PT and DP pulses. Doppler studies do confirm pulsatile flow though. She presented herself to my office on March 9, 1993 with a fourth ray amputation wound, right foot. Regenigel treatments were initiated. The foot healed in six and one-half months.

Patient returned to my office on November 9, 1993 with an infected scar ulceration on the anterior lateral right ankle. Regenigel treatment was started. Patient was placed on Ciprofloxacin. A dermatologist recommended a partial thickness skin graft. I felt this would never heal because of her absent pulsatile flow. Regenigel treatments plus porcine skin grafts combined healed this ulcer in five months and three weeks.

May 6, 1994 the same patient had an abscess of the fifth metatarsal head, right foot. This was incised and drained. Regenigel was applied. Patient was placed on Bactrim. This ulcer healed in three weeks with bi-weekly treatments.

Sub-fifth metatarsal head ulcer re-ulcerated on June 17, 1994 and healed after three weeks of therapy.

July 22, 1994 it re-ulcerated and healed after four days.

On August 2, 1994 it re-ulcerated and healed after five weeks.

On September 16, 1994 the dorsal ulcer re-ulcerated. This took six weeks to heal.

**PATIENT #41:** P.S. is patient number 41. Patient is a 76 year old insulin dependent diabetic with absent pulses. Doppler studies reveal a weak pulsatile PT pulse. Patient presented himself to my office initially on May 7, 1992 with paronychia of the left hallux. I did an incision and drainage. Regenigel was applied after avulsion of the tibial border. This was to be left on one day. Patient to continue with Domboro and silvadene. The infection healed in one week.

Patient returned October 1, 1992 with ulcers on his left leg. They were present for approximately one month. They were secondary to trauma. Regenicel was applied times four days. Patient was placed on Cipro. Patient was to remove Regenicel dressing and apply saline wet to dry. Patient was seen on October 8, 1992. The above treatment was repeated. The above treatment was again repeated October 15, 1992. The ulcers were healed by October 29, 1992, in one month.

Patient returned March 4, 1993 after sustaining trauma to his leg. There were two ulcers present for approximately two weeks. Regenicel was applied times four days. Patient was to apply saline compresses. The ulcers healed in one month.

Patient returned April 1, 1993 after sustaining trauma to his right fifth toenail. I excised the nail. Regenicel was applied times two days. Patient was to apply Silvadene daily. The fifth toe healed in one week.

Patient returned January 31, 1994 with an ulcer under his fifth metatarsal head, left foot. Patient was placed on Clindamycin. Regenicel treatments were started. The ulcer healed in six weeks.

Patient returned May 9, 1994 with an ulcer on his right ankle secondary to trauma. Regenicel treatments were started. The ulcer healed in six weeks.

Patient returned January 4, 1996 with cellulitis and ulceration on his left leg. Regenicel treatments were started. Patient went for by-pass surgery for his left leg.

Patient returned April 15, 1996 with an ulcer on his right heel and an ulcer on his left leg. Regenicel treatments were started. April 30, 1996 a new abscess was seen on his right ankle. This was incised and drained. May 10, 1996 the left foot was healed. This took one month. On May 10, 1996 I did an incision and drainage on an abscess of the distal fibula on the right side. This was also treated with Regenicel treatment. On May 17, 1996 patient developed anterior leg ulcers bilaterally secondary to trauma. Patient was placed on Clindamycin. Regenicel treatments were started here. The next four months Regenicel treatments were used bilaterally on multiple different leg and foot ulcerations. The Regenicel maintained the health of these tissues. On June 9, 1996 patient was moved to a nursing facility. Patient's health declined and eventually patient passed away.

**PATIENT #42:** E.M. is patient number 42. Patient is a 89 year old male with an ulceration on his right hallux with draining white gouty tophus material. Patient has absent DP and PT pulses. There is a faintly pulsatile peroneal pulse confirmed with Doppler. Patient was admitted to Kimball Medical Center for IV antibiotic therapy and saline wet to dry to the above ulceration. This was done on May 31, 1996. Patient was seen in my office June 13, 1996 where the joint was injected with a cortisone preparation and Regenicel treatments began. Patient was also placed on Clindamycin. Patient was seen June 17, 1996. Regenicel was applied times four days, then saline wet to dry to be done by patient. June 29, 1996 Regenicel treatment was performed. Patient was then seen July 1, 1996 and Regenicel was re-applied and patient was to re-apply the Regenicel in three days. Patient was seen July 15, 1996; the ulcer was clean. Regenicel continued times three days. Patient seen July 29, 1996. The ulcer was almost healed. Patient was seen September 3,

1996. The ulcer was very small and clean. Patient was to continue the Regenicel treatment every three days.

**PATIENT #43:** T.H. is patient number 43. This is a 92 year old female with absent pulses. Patient presented herself to my office with a gouty tophus ulceration over her first metatarsal phalangeal joint on her right foot. Initial treatment consisted of betadine and dry sterile dressings daily. This began July 26, 1994. On August 15, 1994, the ulcer was clean. Regenicel treatments every three days were started. On September 16, 1994 debridement was performed and Regenicel was applied. A second debridement was performed September 19, 1994 and Regenicel was applied as a dressing. An extensive debridement was performed September 22, 1994. Regenicel was applied after this. October 26, 1994 a minimal incision bunionectomy procedure was performed at my office. Regenicel treatments continued to February 13, 1995 when the ulcer was totally healed.

**PATIENT #44:** J.T. is patient number 44. He is a 66 year old diabetic male. Patient has weakly palpable pulses. Patient first presented himself to my office on March 30, 1995 with ulcerations under his first and fifth metatarsal heads of his right foot. Regenicel treatments were begun and the ulcers healed in two months and one week.

Patient then returned June 16, 1995 with small ulcers under metatarsals one and five. Two treatments of Regenicel healed the above ulcerations.

Patient returned June 27, 1995 with a small re-ulcerated sub-met five ulcer. Regenicel treatments were prescribed. This healed in five weeks.

Patient returned December 28, 1995 with an abscess under metatarsal five. I did an incision and drainage. Regenicel treatments healed the ulcer in one month.

I saw patient again February 12, 1996 when a sub-met five ulcer reoccurred. I did an incision and drainage. Regenicel treatment healed this in two weeks.

On February 22, 1996 I did a minimal incision surgery i.e. osteotomy of the surgical neck of the fifth metatarsal. Regenicel was applied to the incision. The incision was closed two and one-half weeks later.

**PATIENT #45:** D.H. is patient number 45. She is a 79 year old diabetic female with absent pulses. Patient first came to me with an ulcer on her right heel on March 22, 1996. Regenicel treatments healed this ulcer in three months.

Patient then returned to my office July 25, 1996 after sustaining trauma to her right leg. Regenicel treatments bi-weekly were prescribed. The traumatic ulcer was healed in two months.

**PATIENT #46:** E.B. is patient number 46. This is a 91 year old male with an ulceration on his left hallux. Regenicel treatment began March 20, 1995. Patient was also placed on Cephalexin. An incision and drainage was performed. With two treatments, the ulceration was almost healed.

Patient was seen in my office September 16, 1995 for other podiatric care. The ulcer remained healed.

**PATIENT #47:** W.D. is an 81 year old diabetic male. Patient has absent pulsatile DP and PT pulses, but Doppler's reveal a faintly pulsatile flow. Patient presented himself to my office after having his right hallux amputated secondary to osteomyelitis. Wound was being packed with saline sterile packing. Regenicel treatments began March 31, 1995 and continued for nine months bi-weekly initially, and then weekly. December 28, 1995, after nine months the ulceration was healed. P.S. The above patient was well know to me at the time of the above treatment. He was being seen in my office since 1991 for treatment of diabetic ulcers which healed using the Regenicel treatments.

**PATIENT #48:** R.M. is patient number 48. This is a 79 year old diabetic male with absent pulses. Patient presented himself to my office on September 30, 1996 with an ulcer on the medial side of his right ankle and dorsum of the right foot. Regenicel treatments healed this in one month.

**PATIENT #49:** C.D. is patient number 49. This is a 62 year old insulin dependent diabetic female with absent pulses. Patient presented herself to my office with ulceration in the fourth interspace on the right foot. September 5, 1996 patient was placed on pedi-boro soaks b.i.d., antibiotic ointment, Cephalexin. Patient was seen four days later and Regenicel treatments were prescribed. The ulceration healed in six weeks.

**PATIENT #50:** R.L. is patient number 50. This is a 61 year old patient with absent pulses. Patient presented himself to my office on November 8, 1996 with an infection on the tibial side of his left fifth toe. Regenicel treatments were started as well as Cephalexin antibiotics. The ulcer healed in two weeks.

**PATIENT #51:** R.S. is patient number 51. This is a 83 year old male that had his first metatarsal head excised for a diagnosis of osteomyelitis. On October 25, 1995 Regenicel was started and helped heal a granulating wound. The wound healed in one month.

**PATIENT #52:** M.C. is patient number 52. This is an 85 year old female with an ulcer over the distal aspect of her right foot. Patient lost her toes secondary to frostbite 30 years prior. December 2, 1996 debridement, and incision and drainage were performed; Regenicel treatments were started with dry sterile dressings. Patient was placed on Cephalexin. The ulcerations healed in two weeks.

**PATIENT #53:** M.D. is patient number 53. She is an 87 year old female with a diagnosis of peripheral vascular disease and sclero-derma. This patient is well known to me. For the past five years I have used Regenicel treatments to heal bilateral heel decubitus ulcers, a chronic ulcer over her right first MP joint, and other ulcerations bilaterally. During the latter part of 1996 patient re-ulcerated on her left foot. Regenicel treatments were again started as well as p.o. antibiotics. This treatment on this occasion failed. Patient was admitted to Kimball Medical Center where the second,



third and fourth toes were amputated. Regenicel treatments were used post-operatively. Initially the treatment appeared to stabilize the area, but eventually the areas became necrotic. Patient a below knee amputation.

**PATIENT #54:** B.R. is patient number 54. This is an insulin dependent diabetic male with an ulceration under his first metatarsal head, left foot. Regenicel treatments began August 2, 1996. After four and one-half months the ulcer was healed.

**PATIENT #55:** O.D. is patient number 55. This is a 27 year old black male with a chronic draining ulceration over his right ankle area. Regenicel treatments began July 29, 1996. The ulcerations were healed in four and one-half months.

**PATIENT #56:** M.D. is patient number 56. This is a 93 year old female who sustained trauma to her right leg on March 18, 1996. Patient had absent pulses. Bi-weekly Regenicel treatments healed the above ulcer in one month.

**PATIENT #57:** T.T. is patient number 57. This is a 59 year old insulin dependent diabetic female. Patient came to my office after being treated by another podiatrist for a fractured right great toe. The dorsal medial and lateral aspects of the base of the right hallux had multiple blisters and cellulitis. Regenicel treatments were started and healed the above cellulitis in approximately 10 days.

**PATIENT #58:** A.F. is patient number 58. This is a Laurelton Village Nursing Home patient who had a diagnosis of chronic left third toe ulceration that was being treated with Silvadene cream. I debrided the ulcer on January 15, 1997, applied Regenicel and placed the patient on Keflex. The nurses were instructed as to the application of the Regenicel. Apparently nurses used Telfa over the Regenicel. This is a very occlusive dressing and caused tissue maceration. When I saw patient one week later, the toe was unimproved. Patient was switched back to saline wet to dry dressings b.i.d.

**PATIENT #59:** M.F. is patient number 59. This is also a Laurelton Village Nursing Home patient with an ulcer on her heel. On January 8, 1997 Regenicel treatments were prescribed. I saw patient one week later and the ulcer was 100% improved.

**PATIENT #60:** H.D. is patient number 60. This is an 80 year old female with a small ulcer on her left ankle and abraded erythematous skin. On January 14, 1997 Regenicel treatments were prescribed. After one treatment the areas were 100% improved.

**PATIENT #61:** F.B. is patient number 61. This is a 69 year old insulin dependent diabetic with an ulcer on his ankle. Patient was being treated in the hospital with saline wet to dry without any progress. On January 13, 1997 I began Regenicel treatments. The ulceration was healed in two weeks.

**PATIENT #62** C.L. is patient number 62. This is a 73 year old male with a diagnosis of paronychia of the right tibial and fibula borders of his hallux. Phenol and alcohol cautery procedure was performed on the tibial and fibula borders on January 21, 1997. Regenicel ointment was used in the post-op care successfully.

**PATIENT #63:** F.M. is patient number 63. This is a 79 year old diabetic smoker with gangrenous changes bilaterally to his heels. Regenicel treatments began January 12, 1997 and were performed bi-weekly. Patient was non-compliant with respect to keeping the heels non-weight bearing. Approximately one month later, he developed a new area of gangrene. I referred patient to a vascular doctor for amputation.

**PATIENT #64:** J.M. is patient number 64. This is a 90 year old male with cellulitis on his left ankle. On February 3, 1997 I applied Regenicel, an unna boot, and cortisone cream to inflamed skin. Four days later, the areas were 100% improved.

**PATIENT #65:** R.D. is patient number 65. This is a 90 year male with absent pulses. Patient presented himself to my office on January 28, 1997 with an abscess and small ulceration on the plantar distal aspect of his right hallux. I performed an incision and drainage. Patient was placed on Cephalexin and began Regenicel treatments. Two months later, the ulceration was totally healed.

**PATIENT #66:** C.F. is patient number 66. This is an 88 year old female who is on Trental and has absent DP and PT pulses. Patient sustained trauma to her left leg on December 11, 1996. Traumatic event created a gash in her skin. Regenicel treatments were prescribed and continued every two to three days by patient. The skin went on to heal.

**PATIENT #67:** E.K. is patient number 67. This is an 80 year old female with absent pulses. Patient presented herself to my office on February 17, 1997 with a small ulceration on the lateral side of her left ankle. Regenicel treatments were started. Ulcer healed in one week.

Patient #	Initials	Tx Episode	Age	Diabetes	Absent Pulses	Diagnosis	Weeks Till Cure	Tx Failure	Adverse Reaction
1	G.R.	1	58	X	X	Ulceration R Foot	10		
2	G.G.	1	61	X	X	Ulceration R Heel	1		
		2				Ulceration R Heel	111		
3	W.J.	1	80		X	Ulcerations Legs	13	**	
		2				Ulcer L Leg	1		
		3				Abscess L Midfoot	2		
		4				Ulcers	1		
		5				Ulcers	5		
		6				Ulcers	3		
		7	81			Leg Abscesses	12		
		8				Cellulitis	3		
		9				Leg Ulcers	13		
		10				L Leg Ulcers	3		
		11	82			Posterior R Leg Ulcer	6		
		12				Ulcers	12		
		13				Trauma To Legs	9		
		14				Ulcers L Legs	6		
		15				Bilateral Leg Ulcers	21		
4	J.B.	1	56	X		Cellulitis L 2nd Toe	2		
		2				Cellulitis R Leg	2		
		3	57			Ulcer L Leg	5		
		4	58			Infection R Midfoot		X	
5	A.F.	1	83		X	Ingrown R Hallux Nail	1		
		2	86			Ulcer R 5th Toe	5		
		3				Ulcer R 5th Toe	5		
6	A.L.	1	63	X		Infected Fissure R Heel	2		
		2				Leg Trauma	2		
		3				Hematoma L Leg	1		
		4				Abscess L 3rd Toe	6		
		5				L Leg Ulcer	5		
		6	64			Ulcer R Foot	5		
7	M.R.	1	60	X		Ulcer R 3rd Toe	1		
		2				Ulcer L Ankle	1		
		3	61			Ulcer L Leg	1		
		4				Ulcer 4th Toe	13		
		5	62			Abrasion L Hallux	4		
		6				Fissure L Hallux	1		
		7	63			Ulcer L Ankle	2		
		8				Ulcer R Ankle	4		
		9				Ulcer L Ankle	2		
		10				L Leg Ulcer		X	
8	A.B.	1	73	X	X	Chronic R Hallux Ulcer	11		
		2	74			Ingrown R Hallux Nail	2		
9	Z.P.	1	82			Infected Ulcers R Leg	3		
10	S.L.	1	74	X	X	Ulcer L 1st M.P. Joint	1		
		2				Ulcers L Forefoot and Toes		X	
11	J.G.	1	71		X	Decubitus Ulcer R Heel	13		
12	M.G.	1	67	X	X	L Heel Ulcer	4		
		2				R Hallux Ulcer		X	
		3	69			R Hallux Ulcer	13		

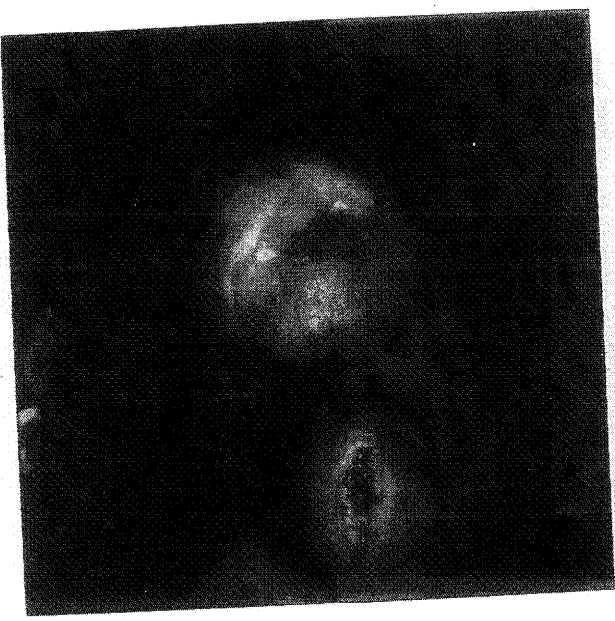
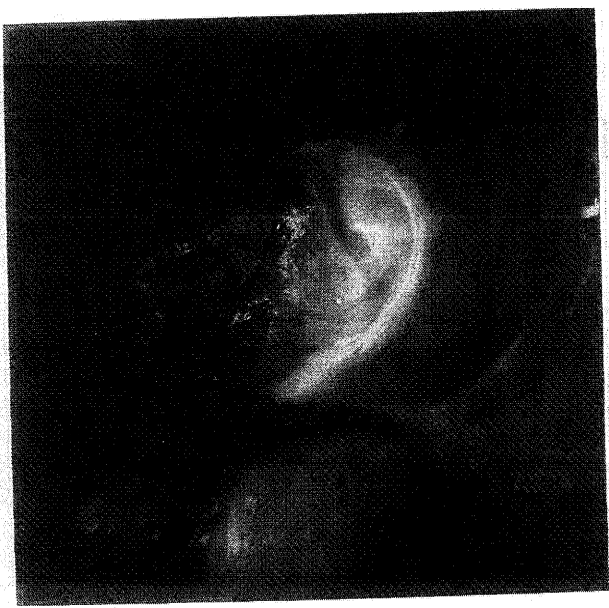
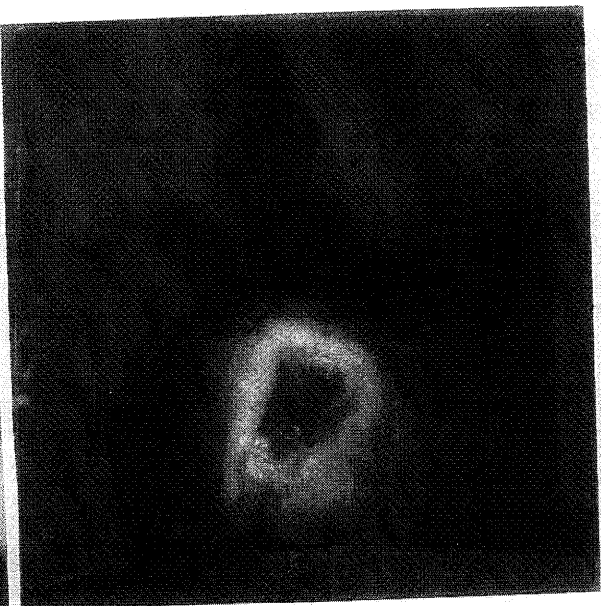
Patient #	Initials	Tx Episode	Age	Diabetes	Absent Pulses	Diagnosis	Weeks Till Cure	Tx Failure	Adverse Reaction
13	W.W.	1	64		X	Gangrene R 5th Toe	10		
		2				Ulcer L Heel and Leg	17		
		3				5th Metatarsal Ulcer	4		
		4				Posterior R Leg Ulcer	18		
		5				L Heel Ulcer	2		
		6				L Leg Ulcer	2		
		7				R Leg Ulcer	2		
14	B.A.	1	92	X		Gouty Ulcer	4		
		2				Gouty Ulcer 3rd Toe	1		
15	F.D.	1	75	X		Delayed Healing R Leg Incisions	1		
16	G.F.	1	84		X	Paronychia L Great Toe	5		
		2				Ulcer L 4th Toe	5		
		3				Ulcer L 4th Toe	1		
		4				Ulcer L 4th Toe	2		
		5				Ulcer L 4th Toe	2		
17	C.G.	1	88		X	Ulcer 3rd Toe	4		
		2				Ulcers 2nd and 4th Toes	10		
		3				Ulcer L Hallux	39		
		4				Ulcer 2nd Toe L	9		
		5				Ulcers L Hallux, L 2nd and 3rd Toes	48		
18	M.P.	1	79			Ulcer Plantar	1		
		2				Metatarsal Head 1 R Ulcer Plantar R Foot	2		
19	J.K.	1	80		X	Chronic Ulcer L Foot	22		
20	E.M.	1	78		X	Osteomyelitis L Hallux		X	
		2				3rd Toe Ulcer	4		
21	R.D.	1	75	X		Ulcer Plantar Medial L Foot	16		
22	S.B.	1	55	X		Chronic R Foot Ulcer	4		
23	F.E.	1	96			Ulcer R Ankle	2		
		2				Decubitus Ulcers Heels	6		
24	B.D.	1	74		X	Ulcer 4th Toe L Foot	13		
25	K.I.	1	74	X		Infected Ulcer L Leg	3		
26	A.M.	1	59	X		Leg Ulcers	6		
27	W.F.	1	61			Delayed Primary Closure vs Regenicel	1		
28	N.M.	1	75		X	Ulcer 2nd Toe L	1		
		2				Ulcer 2nd Toe R	3		
		3				Ulcer 4th Toe L	18		
29	T.M.	1	31			Chronic Venous Ulcer R Ankle	3		
		2				Venous Ulcer R Ankle	4		
		3				Venous Ulcer R Ankle	1		
		4				Venous Ulcer R Ankle	3		
		5				Venous Ulcer R Ankle	1		
30	R.H.	1	65	X	X	Infected L Hallux	1		
		2				R Hallux Ulcer	1		
		3	66			Infection R 3rd Toe	2		
		4				Fissure R Forefoot	3		
		5				L Hallux Ulcer	3		
		6				Abscess R 3rd Toe	3		

Patient #	Initials	Tx Episode	Age	Diabetes	Absent Pulses	Diagnosis	Weeks Till Cure	Tx Failure	Adverse Reaction
		7	67			Trauma L Hallux	2		
		8				Abrasion Plantar R Foot	1		
		9				Trauma L Hallux	2		
		10	68			Abscess R 3rd Toe	1		
		11				Trauma L Hallux	1		
		12	69			Abscess R 2nd Toe	18		
		13	70			Trauma L Hallux	3		
		14				Infected L Hallux	56		
31	J.M.	1	62	X		Abrasion L Great Toe	8		
32	A.G.	1	78	X	X	Paronychia R Hallux	2		
		2				Abscess R Great Toe	2		
33	A.M.	1	75			Chronic Ulcer L Leg	19		
		2	76			Ulcers L Leg, L 5th Met Head, R Leg, and Dorsum R Foot	4		
34	G.K.	1	85		X	Ulcer L Leg	5		
35	L.O.	1	61			Ulcer L Leg	48		
36	W.S.	1	60	X		Ulcers R Foot	3		
37	J.P.	1	55	X		Post Op Wound Dehiscence	1		
38	C.A.	1	72			Chronic Ulcer R Ankle	5		
		2	74			Ulcer R Ankle	1		
39	L.P.	1	72		X	Chronic Venous Ulcer L Leg x5Years	6		
40	F.M.	1	75		X	Surgical Wound R Foot	28		
		2				Infected Scar R Ankle	25		
		3				Abscess Plantar Metatarsal 5 R Foot	3		
41	P.S.	1	76	X	X	Paronychia L Hallux	1		
		2				Ulcer L Leg	4		
		3	77			L Leg Ulcers	4		
		4				Trauma R 5th Toe Nail	1		
		5	78			Ulcer Plantar 5th Met Head L Foot	6		
		6				Ulcer R Ankle	6		
		7	79			Ulcer L Leg		X	
		8				Ulcer L Heel	4		
		9	80			Ulcers R Heel and 5th Metatarsal		X	
42	E.M.	1	89		X	Infected Gouty Tophus R Hallux	16		
43	T.H.	1	92		X	Gouty Ulcer R 1st M.P. Joint	26		
44	J.T.	1	44	X		Ulcers Sub Met 1 And 5 R	10		
		2				Ulcers Sub Met 1 And 5 R	1		
		3				Ulcer Sub Met 5	6		
		4				Abscess Sub Met 5 R	4		
		5				Abscess Sub Met 5 R	1		
		6	45			Delayed Healing Minimal Incision Surgery Incision	2		

Patient #	Initials	Tx Episode	Age	Diabetes	Absent Pulses	Diagnosis	Weeks Till Cure	Tx Failure	Adverse Reaction
45	T.H.	1	79		X	Trauma R Leg	8		
		2				Ulcer R Heel	13		
46	E.B.	1	91		X	Ulcer L Hallux	1		
47	W.D.	1	81	X	X	Amputation Wound R Hallux	39		
48	R.M.	1	79	X	X	Ulcers Medial Side R Ankle and Foot	3		
49	C.B.	1	62	X	X	Ulcer 4th Interspace R	6		
50	R.L.	1	61		X	Ulcer L 5th Toe	1		
51	R.S.	1	83	X		Surgical Wound R Foot	5		
52	M.C.	1	85			Ulcers R Foot	2		
53	M.D.	1	85		X	Scleroderma, Heel	40		
						Ulcers, Toe Ulcers, R Bunion Ulcer			
		2	87			Necrotic L 3rd and 4th Toes		X	
54	B.R.	1	59	X		Ulcer Plantar 1st Met Head	19		
55	O.B.	1	27			Chronic R Ankle ULCER	22		
56	M.D.	1	93		X	Abrasion R Leg	4		
57	T.T.	1	59	X		Abscess R Hallux	2		
58	A.F.	1	88		X	Ulcer L 3rd Toe		X	
59	M.F.	1	80		X	Ulcer R Heel	8		
60	H.D.	1	80		X	Abrasion R Leg	1		
61	F.B.	1	69		X	Infected Fissure	2		
62	C.L.	1	73			Phenol and Alcohol Procedure	3		
63	F.M.	1	79	X		Gangrene L Heel		X	
64	J.M.	1	91			Cellulitis Leg	1		
65	R.G.	1	90		X	Abscess Plantar R Hallux	8		
66	C.F.	1	88		X	Gash L Leg	4		
67	E.K.	1	80		X	Ulcer L Ankle	1		
67		161	71.8	48%	63%		8	12	0

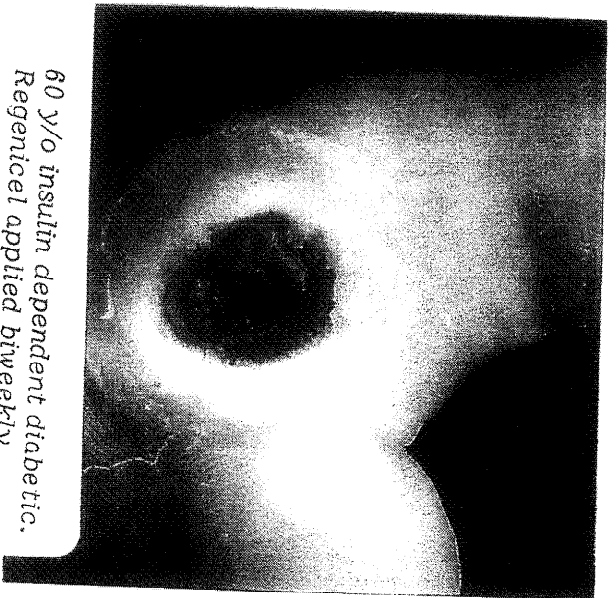
## Appendix A

1. Polysporin Powder - Warner Wellcome Consumer Health Products<sup>4 4</sup>  
Morris Plains, N.J. 07950 U.S.A.
2. Vitamin A @ Vitamin D Ointment- E. Fougera @ Co.  
Melville, New York 11747
3. Vitamin E Oil- Jason Natural Cosmetics  
Culver City, CA 90232-2484



T.S. 77 Year Old Diabetic  
 Absent Pulses  
 Pulsatile PT & Peroneal With Doppler  
 No Pulsation to Hallux  
 4/20/94 Biweekly Regenicel  
 Antibiotics, Debridements  
 Healed: 8/4/94

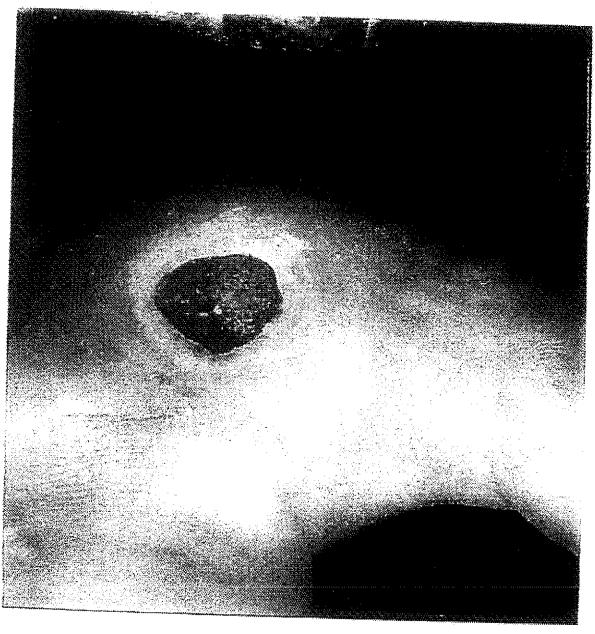




60 y/o insulin dependent diabetic.  
Regenigel applied biweekly.

8/2/96

54



54

10/25/96



54

CASE 18



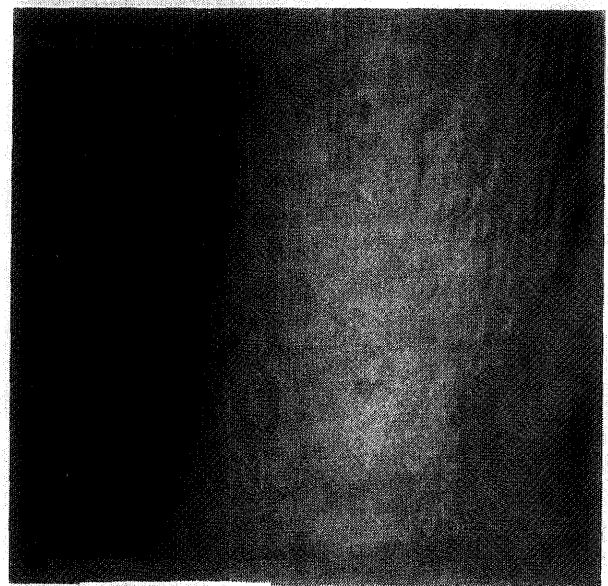
Left leg 6/17/98



2.5 cm x 2.5 cm  
7/6/98



10/2/98



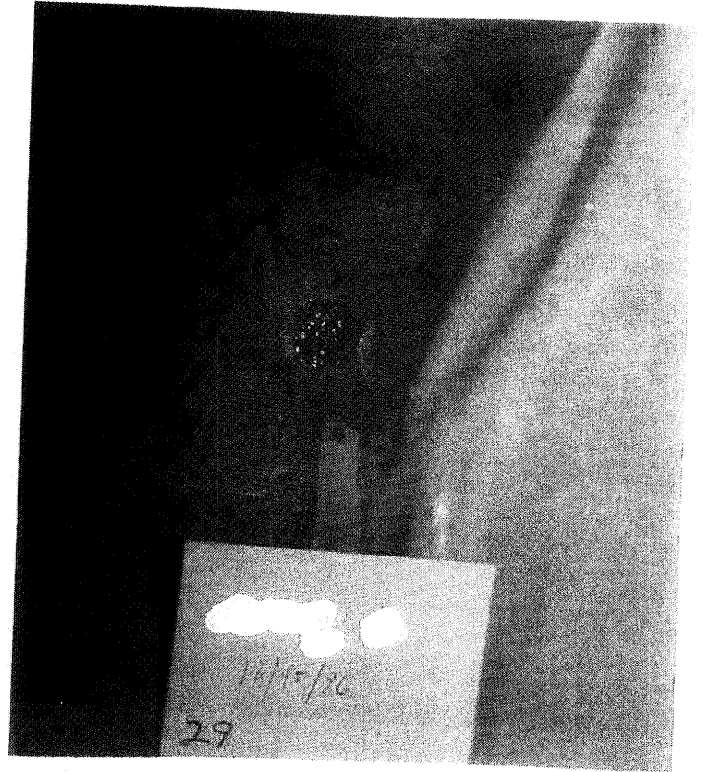
12/16/98

69 year old Diabetic, ulcer posterior, legs.  
First treated 12/97 by infectious disease M.D.,  
then wound care center. Silvadene failed to  
help.

Dopplers revealed faint D.P. and P.T. LEFT.  
Treatment: Oral antibiotics initially, cortisone  
to inflamed skin, Regenicel and unna boots  
biweekly.



29



11/18/96



Chronic venous ulcers treated with procurin  
silvadiene and saline for two years.  
Regenicel and unna boots closed this ulcer  
in five weeks.  
Regenicel and compression has kept the  
patient healthy for the past two years.

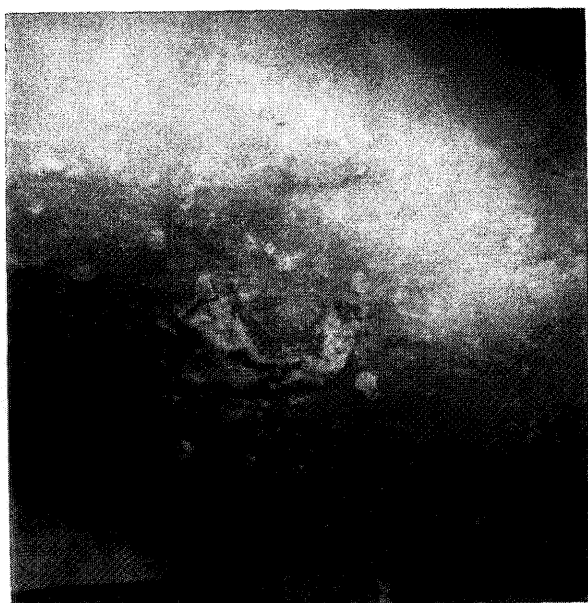
11/22/96



7/2/98



8/3/98



9/24/98



10/8/98

91 Year Old Female with Chronic Ulcers  
Left Leg and Foot.  
Treatment has consisted of Silvadiene Cream  
and Unna Boots by Vascular MD for past  
six weeks.  
Patient states that ulcers are getting worse.  
Dopplers reveal a very weak Dorsalis Pedis  
Pulse on Left Side.  
Regenicel Ointment and Unna Boots began  
on July 2, 1998.

DONALD N. PHAIR  
1788 BUTTONWOOD AVE.  
TOMS RIVER, NJ 08755-0816

Dec 10, 2000

Dr. Leslie Aufseesser  
1700 Madison Ave  
Lakewood NJ 08701

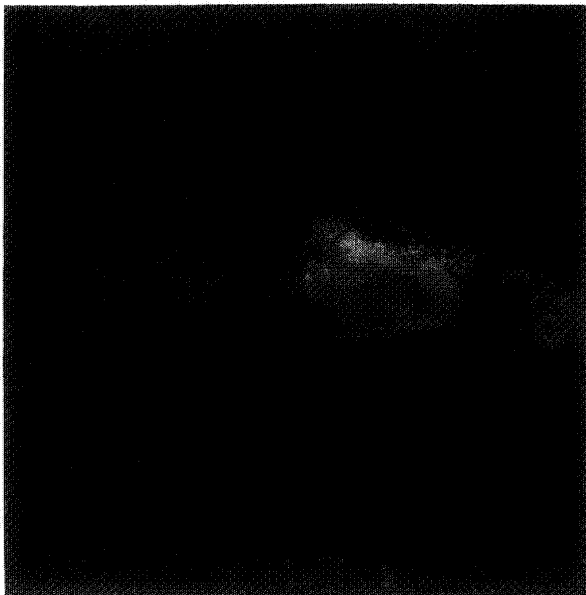
Dear Dr.

I wish to commend you on your Regenerel First Aid Antibiotic Ointment. Last year I had a ulcerated wound on my ankle which I could not get rid of until I went to see you. You applied your Regenerel ointment and wrapped the wound for four or five weeks. It completely cured the wound. I have used the ointment for minor cuts, split fingers, etc. and I'm always amazed how well it cures.

This product should be made available to all by making it available in drug stores. Now it is only available at your office.

Yours truly  
Donald N Phair





Veda Thompson  
5/28/98



12x3mm  
6/2/98

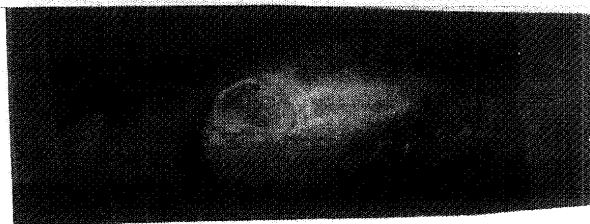


5/19/98



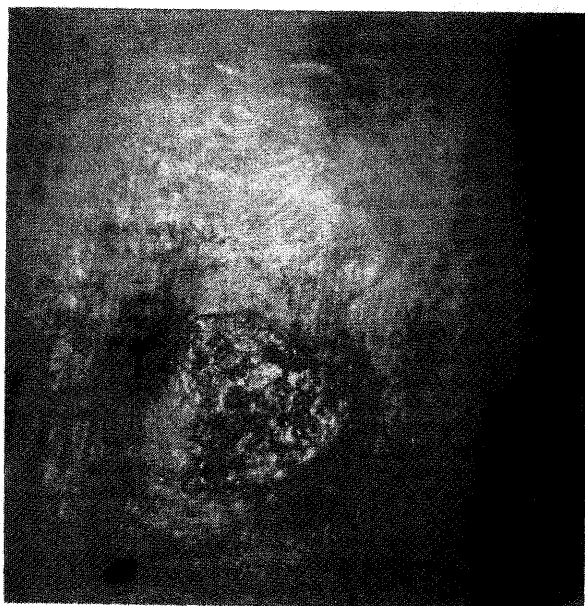
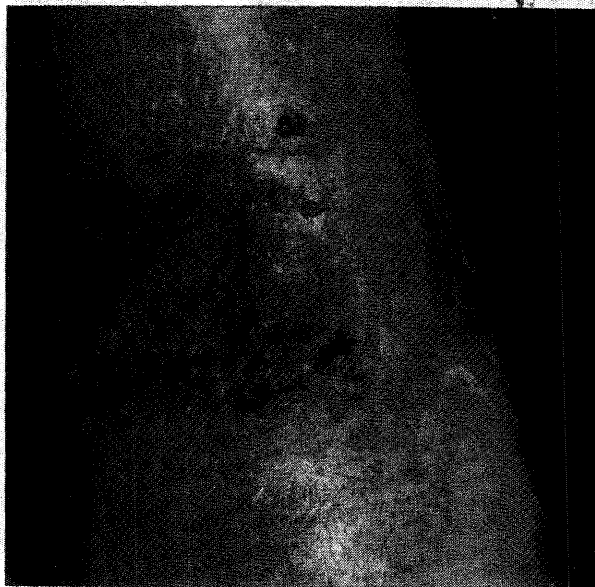
2/10/98  
Thompson, Veda

A 70 Year Old Diabetic Female.  
Silvadiene used for 3 weeks, wasn't helping.  
Patient takes Diabeta  
Only a very faint P.T. Pulse could be picked  
up with Doppler.  
PPG Wave totally flat to Left 5th toe  
Regenicol started 5/28/98



5/11/98

(R)  
L2  
3x2.5  
cm  
BR 01/24/01



1-26-01

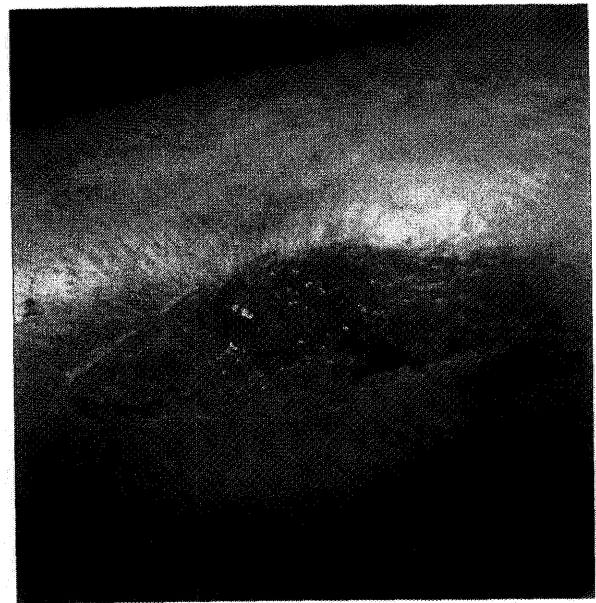


2-2-01

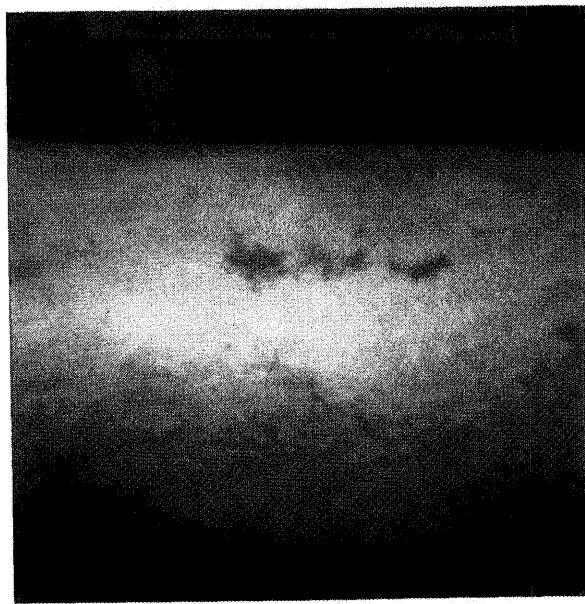
69 Year old female allergic to sulfa  
One month old wound anterior right  
leg, good pulses present.  
Debridement, cipro for one week.  
Regenicol ointment started 1/24/01



1/2/01  
 2nd leg + 1st  
 PSL wings



1/8/01



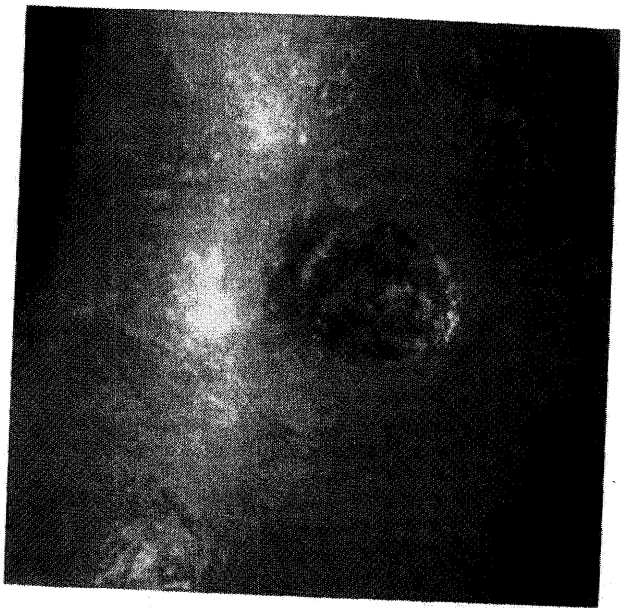
2/13/01

83 Year old female with wound left leg getting worse with neopsorin ointment.

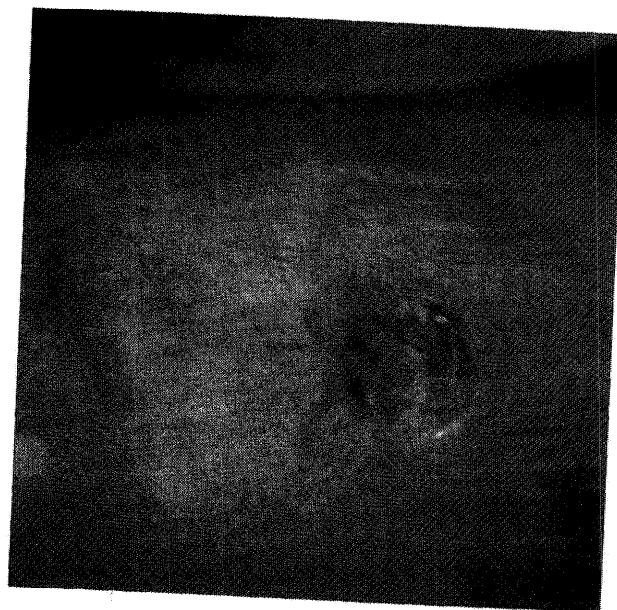
Dopplers reveal pulsatile DP & PT pulses.

Regenicel started 1/2/01 & cephalixin 500 x 1 ~~week~~ also started 1/2/01.





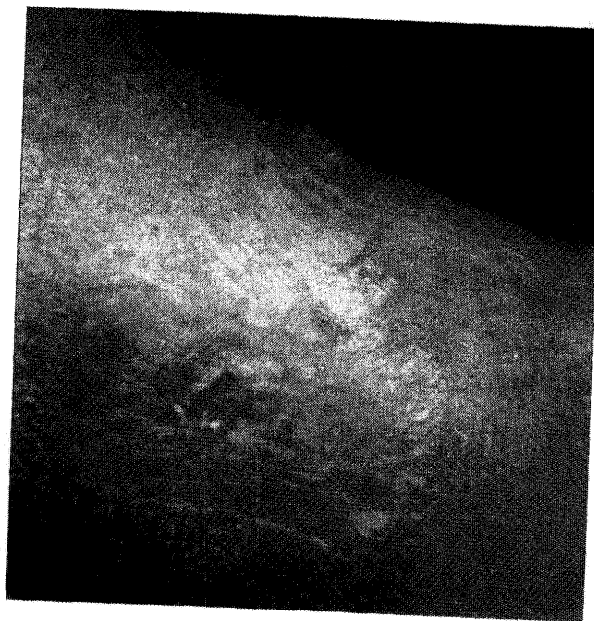
1.5x  
2cm  
40x  
R  
L  
7/9/01



7/16/01  
R  
20x  
25x  
15x  
mm



8/24/01  
R  
15x  
12mm



10/7/01

CHAI ROSEN FRIED  
10-16-19 O.O.B. 8/17/02



2-1-01 1cm .75cm  
(R) mid, 150



5/25/01



7/13/01 5mm X 5mm



3mm X 3mm 10/5/01

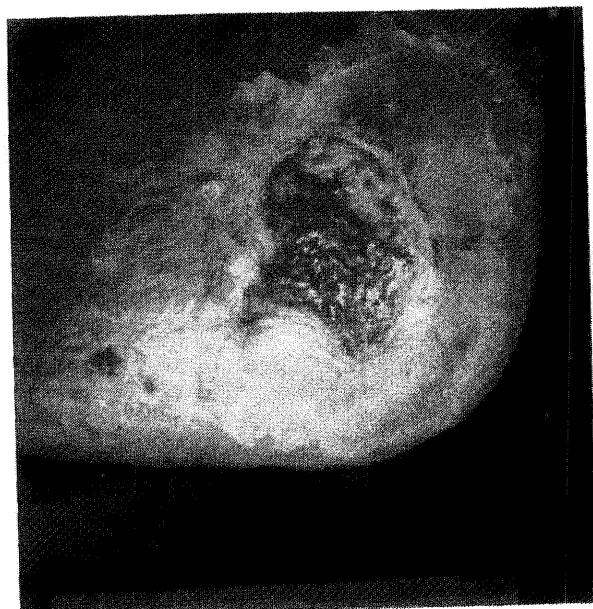
AUGUST VOGEL 8/9/20 D.O.B 8/4/0

INSULIN DEPENDENT DIABETIC.  
Dopplers reveal faint pulsatile flow.



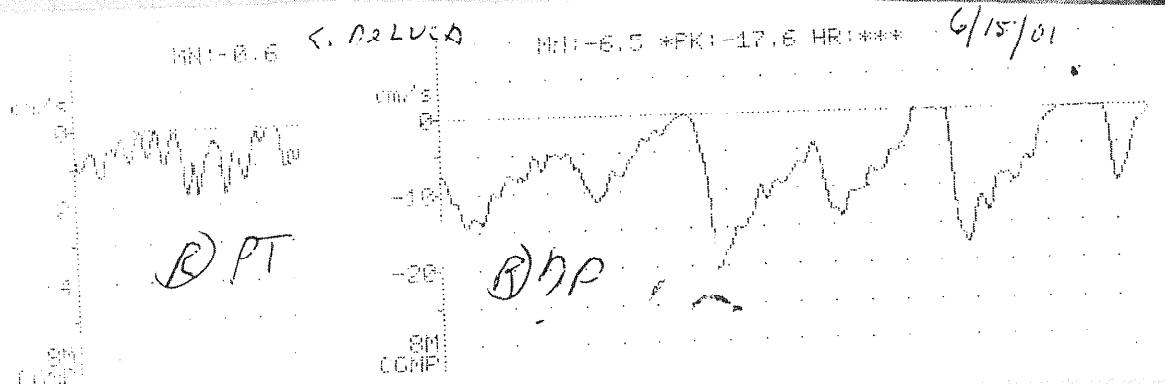
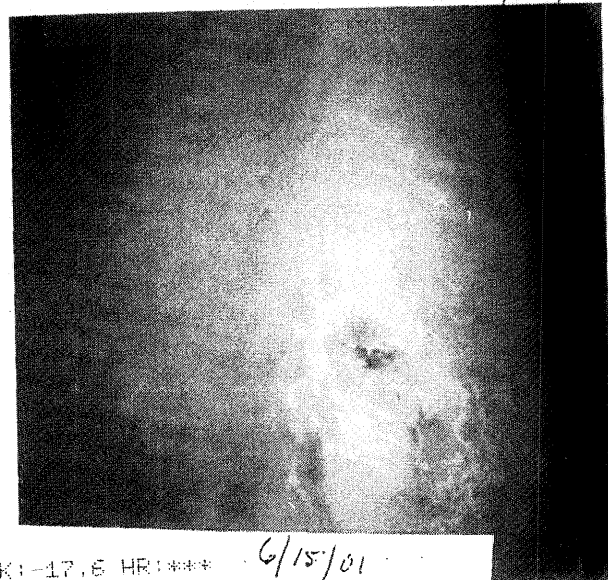
R heel - 6/15/01  
post debrid

R heel 6/24/01 2x1.8cm



R heel 7/5/01  
post debrid

8/20/01



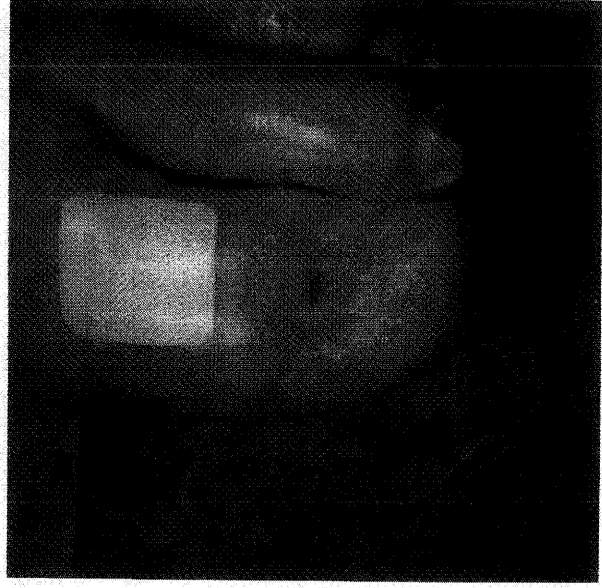
CARMINE DELUCA D.O.B. 10/28/37

Diabetic, heart disease, kidney disease.  
Right heel ulcer - Healed in two months.





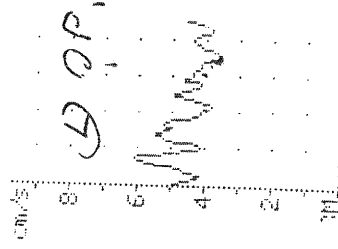
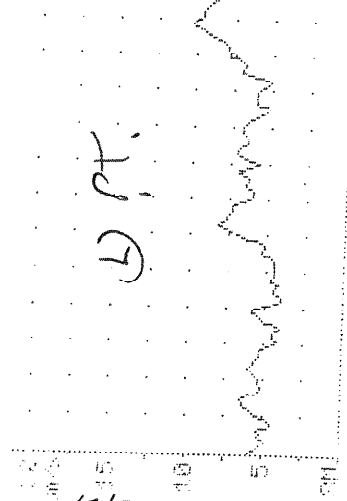
Charles Hargreaves 8/24/00



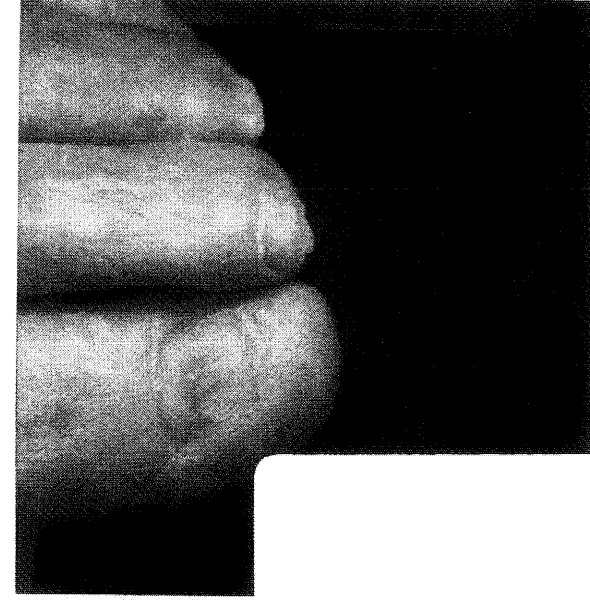
8/25/00



Charles Hargreaves  
8/22/00



8/27/00



8/30/01

Charles Hargreave

D.O.B. 9/17/19

80 y/o Diabetic, PVD, Bladder Cancer  
Infected right hallux nail  
Avulsion 3/2/00  
Regenigel started  
Healed in one year!

# Atlantic Coast

Rehabilitation and Health Care Center

September 17, 2001

Leslie Aufseeser, DPM  
1700 Madison Avenue,  
Lakewood, NJ 08701

Dear Dr. Aufseeser,

With deepest gratitude I write this letter of appreciation for the talented care you provided my grandmother.

Before you became involved in this complicated wound of the first metatarsal phalangeal joint space, we were told that a portion of her toes and foot might need to be amputated.

When you first arrived and saw this wound you gave us hope for a natural recovery. "Regenicel," a special compound that you created, was applied two times a day and after several weeks she was completely healed. I repeat, completely healed.

May God give you continued success and the best of health to you and your family.

Very truly yours,

  
Simon Shain, LNHA  
Administrator

Madeline M. Rossi  
21 Santo Domingo Dr  
Toms River, NJ 08757-6434

Oct. 23, 2000

Dr. L. Aufseeser  
Lakewood, N.J.

Dear Dr. Aufseeser -

Just a brief note to tell you how  
pleased I am with your treatment  
and your miracle salve you used  
on my wounded leg. Your salve  
healed my leg in just three visits  
to your office and I did not have to  
apply the salve every day, you  
said every two or three days and  
just once a day would be sufficient.

Before going to your office, I had  
been to the emergency room at  
the hospital and to two other doctors,  
no one was able to help me until I  
came to your office.

Thank you once again doctor for  
all your help and your wonderful  
treatment.

Sincerely,

Madeline Rossi

January 18, 2001

Dr. L. Aufseeser  
Lakewood Plaza  
Route 9 and Kennedy Blvd.  
Lakewood, NJ 08701

Dear Dr. Aufseeser,

I would like to take this opportunity to thank you for the wonderful care you gave my husband during his recent episode involving a severe infection of his foot.

As you probably recall, my husband sustained a small wound on his foot that refused to heal, eventually causing an infection to permeate deep into his skin. To prevent the infection from reaching the bone, the wound was surgically scraped and cleaned. This required a lengthy recuperation period during which my husband was limited to a wheelchair, and thus virtually homebound.

Perhaps due to his age (79) the surgical site healed extremely slowly. This placed a tremendous strain on myself and my children, since my husband continued to be weak and incapacitated, and needed to be cared for practically twenty-four hours a day.

This was the point at which we arrived at your office, and were fortunate enough to have you treat my husband with your 'magic ointment'. Although we had heard about your special formula, we were truly astounded to witness its potent healing power first-hand. Literally within a few applications, the wound healed, enabling my husband to walk freely once more, as well as care for most of his needs. Thank you from my husband, myself, and my children!

Please accept our wishes for your continued success in treating patients with this wonderful cream that you have formulated. It has truly been a blessing to our family, as I am sure it has been to many others in the past, and will continue to be in the future.

Very sincerely yours,



Mrs. Henchie Weisberg  
900 Forest Avenue  
Lakewood, NJ 08701

DR. LESLIE S. AUFSEESER  
1700 MADISON AVENUE  
ROUTE 9, KENNEDY BLVD.  
LAKEWOOD N.J. 08701

Fold at line over top of envelope to the  
right of the return address

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P 342 682 836

**MAIL**

★ ★ ★ UNITED STATES POSTAGE  
193 PB8692453  
5461 # 07.350 OCT 29 01  
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TO: HFA-305 ROOM1061

# OF PCS: 1



7810025005248

RM:

HFA-305 ROOM1061

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ROOM 10-61  
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